

PERINATAL HEPATITIS B PREVENTION PROGRAM MANUAL



**Perinatal Hepatitis B Prevention Program
Infectious Disease Epidemiology and Response
Bureau of Epidemiology and Public Health Informatics
Kansas Department of Health and Environment
1000 SW Jackson, Suite 210
Topeka, Kansas 66612-1290
Telephone (785) 296-1059 Fax (785) 291-3775
Reporting Hotline: Telephone (877) 427-7317 Fax (877) 427-7318**

TABLE OF CONTENTS

Chapter One: Introduction to Hepatitis B3
 Clinical Features and Epidemiology3

Chapter Two: Detecting and Preventing Hepatitis B.....7
 Diagnosis7
 Prevention 10
 Hepatitis B Immune Globulin 10
 Hepatitis B Vaccine 10
 Serological Testing 13

Chapter Three: Perinatal Hepatitis B Prevention Program Objectives..... 14

Chapter Four: Kansas State Public Health Law 17

Chapter Five: Case Identification and Information Transfer 18
 Reporting Sources 18
 Information Transfer 19

Chapter Six: Role of Local Health Departments in Case Management and Tracking..... 21
 Case Investigation..... 21
 Contact Investigation..... 22
 Case Management 22
 Contact Management 22
 Education 24
 Data Management and Reporting to KDHE 25
 Checklist for Local Health Departments 30

Chapter Seven: Role of Prenatal Care Providers in Case Management 31
 Checklist for Prenatal Care Providers..... 32

Chapter Eight: Role of Hospitals in Case Management..... 33
 Policy Recommendations..... 33
 Prophylaxis of Infants..... 34
 Checklist for Hospitals 38

Chapter Nine: Role of Pediatric Care Providers in Case Management 39
 Identification and Management..... 39
 Vaccination 39
 Checklist for Pediatric Care Providers..... 43

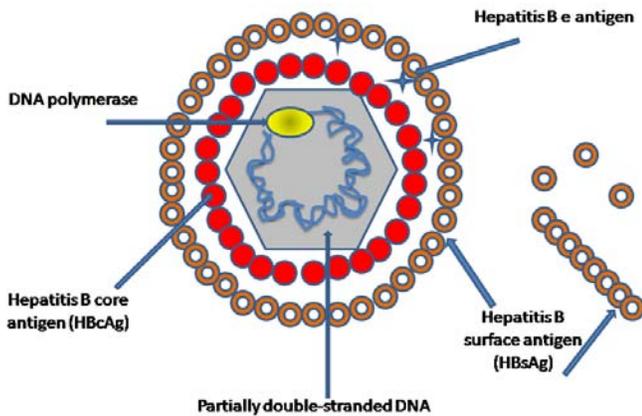
References 44

Appendices 46
 Appendix A – Laws 47
 Appendix B – Reporting Forms 51
 Prenatal Care Provider Report Form 52
 Hospital Report Form 53
 Pediatric Provider Report Form 54
 Appendix C – Kansas Notifiable Disease Form 55
 Appendix D – Letters for Providers 56
 Letter for Prenatal Care Providers 57
 Letter for Pediatric Care Providers, pre-delivery 58
 Letter for Pediatric Care Providers, post-delivery 59
 Letter for Hospitals..... 60
 Appendix E – Additional Resources 61

Hepatitis B Virus

Hepatitis B virus (HBV) is a small, double-shelled virus in the family Hepadnaviridae. The virus has a small circular DNA genome that is partially double-stranded. HBV contains numerous antigenic components including hepatitis B surface antigen (HBsAg), hepatitis B core antigen (HBcAg), and hepatitis B e antigen (HBeAg) (Figure 1.1). Humans are the only known host for HBV. HBV is relatively stable and has been shown to remain infectious on environmental surfaces for more than 7 days at room temperature (1). Once a susceptible person is exposed to hepatitis B virus, the virus travels through the bloodstream to the liver where replication occurs (2).

Figure 1.1 Simplified Drawing of Hepatitis B Virus Components



Marker	Abbreviation
Hepatitis B Surface Antigen	HBsAg
Hepatitis B Core Antigen	HBcAg
Hepatitis B “e” Antigen	HBeAg

Clinical Features and Epidemiology

Signs and Symptoms

HBV can cause an acute or chronic infection, both of which may be asymptomatic. Approximately 10% of children and 30-50% of adults who contract hepatitis B will exhibit symptoms (3). **Acute hepatitis** symptoms are similar to other symptoms caused by other hepatitis viruses and range from an asymptomatic infection to a prodromal illness with non-specific symptoms (such as anorexia and malaise) followed by jaundice. Symptoms frequently seen are anorexia, malaise, nausea, jaundice, vomiting, right upper quadrant pain and dark urine (4); however, approximately 50% of adults with an acute hepatitis B infection are asymptomatic (1).

Following infection with HBV, the risk of progressing to a **chronic infection** (defined as testing positive for hepatitis B at least 6 months apart, or the presence of hepatitis B virus in the blood and an absence of the immunoglobulin M subclass (IgM) antibody to hepatitis B core antigen) is dependent on age (4); approximately 90% of infants infected at birth, 30%-50% of children from one to five years of age, and 6% to 10% of older children and adults will become chronically infected (3). Most chronically infected adults with HBV do not develop chronic liver disease. However, patients may have elevated serum aminotransferase levels, inflammation and hepatocellular necrosis, or fibrosis of the liver; symptoms during this time are generally nonspecific. If a patient develops cirrhosis (scarring of the liver) then symptoms (e.g., jaundice, loss of appetite, etc) become more prominent. Hepatocellular carcinoma develops in 0.5% of patients with chronic HBV infections and 2.4% of patients with cirrhosis, annually. Additionally, there are an estimated 500,000 to 1,000,000 deaths annually worldwide, due to hepatitis B infection (2). In the United States, it is estimated that approximately 800,000 – 1.4 million persons are living with chronic HBV infection, and 3,000- 4,000 persons die from HBV related cirrhosis. Additionally 1,000 – 1,500 persons die each year from HBV-related liver cancer (1).

There are 5 phases associated with hepatitis B virus infections: incubation period, prodromal or preicteric phase, icteric phase, convalescence phase, and the recovery or persistence phase (Table 1.1).

The **incubation period** from exposure to jaundice onset for HBV is 45-160 days (average, 120 days) (1) (4). The time from exposure to abnormal serum alanine aminotransferase (ALT) levels is 40 to 90 days (average, 60 days) and the time from exposure to detection of HBsAg in the serum is 30-60 days and persists for variable periods (1).

The **prodromal phase**, or **preicteric**, lasts between 3 and 10 days and is defined as the time from initial symptoms to jaundice onset. The manifestations are non-specific and include anorexia, nausea, malaise, vomiting, right upper quadrant abdominal pain, and dark urine; additionally, cases may present with extrahepatic symptoms such as arthralgia, arthritis, and skin rashes (5).

The **icteric phase** typically lasts from 1 to 3 weeks and is characterized by jaundice, light or gray stools, hepatomegaly, and hepatic tenderness (5).

During the **convalescence phase**, fatigue and malaise may continue for weeks or months while other symptoms, such as jaundice and anorexia disappear (5).

The **recovery or persistence phase** occurs in the months following infection, when it becomes evident whether an HBV infection will resolve or become persistent (5).

Table 1.1: Hepatitis B Clinical Course (1)

Phase	Characteristics	Duration
Incubation	Time from exposure to first symptoms	45 – 160 days
Prodrome	Non-specific illness that precedes jaundice	3-10 days
Icterus	Jaundice (dark urine and yellow discoloration of sclera); occurs variably in adults	1-3 weeks
Convalescence	Period of resolution of jaundice; fatigue and malaise present	Weeks or months
Recovery or persistence	In the months after HBV infection, it becomes evident whether an infection will persist or resolve	

Transmission

HBV is transmitted by **percutaneous** and **mucosal** exposure. **The highest concentrations are found in blood** while lower concentrations of HBV are found in saliva and semen. Saliva has been shown to transmit HBV through bites; however, other types of exposure to saliva are unlikely modes of transmission including through kissing. Additionally, there is no evidence of transmission via sweat, tears, stool, urine, or droplet nuclei. All people who are infected with HBV are infectious. HBV is also highly stable in the environment and can remain viable for at least 7 days when present on an environmental surface at room temperature. Furthermore, HBV can be present at concentrations of 10²⁻³ virions/ml without any visible blood, and can cause transmission (1).

Sexual intercourse remains the most frequent transmission route in the United States (1). Hepatitis B virus has been found to be 50 to 100 times more infectious than HIV (6), and even though HBV is present in semen at levels of 100- to

1000-fold lower than blood, sexual intercourse has been shown to be an effective transmission route. As the number of partners increases, there is a greater risk for HBV infection in both heterosexual individuals and men who have sex with men (5).

Percutaneous transmission occurs when an object tainted with HBV infected blood punctures the skin. This method of transmission occurs most frequently with injection drug users who share needles. Additionally, transmission may result from tattooing, ear piercing, and acupuncture, as well as needlesticks and other similar health care associated injuries with sharp medical instruments. (1). Transmission via blood products is rare in developed countries due to the screening of blood donors for HBsAg. However, transmission through transfusions and medical injections remains common in developing countries due to a high percentage of people being HBsAg positive (10% or higher) (5).

Per mucosal transmission occurs when infective plasma or serum contaminates mucosal membranes, such as the eyes or mouth. This may occur during eye splashes, mouth pipetting, hand-to-eye and hand-to-mouth contact when hands are contaminated. Transfer of HBV to skin lesions or mucous membranes via contaminated inanimate environmental surfaces may occur. Contamination of mucosal surfaces with infective secretions other than serum or plasma could occur with contact involving semen (1).

Horizontal transmission can occur in households when one member is HBV positive. While the particular mechanism is unknown, it is hypothesized that transmission is due to frequent contact with blood-containing secretions or possibly saliva. Additionally, as HBV is highly durable in the environment, transmission may be due to sharing objects such as toothbrushes, washcloths, razors, and towels (4).

Perinatal transmission (transmission from mother to child) is a highly efficient method of transmission that occurs when the infant is exposed to blood during labor and delivery. *In utero* transmission accounts for less than 2% of perinatal infections. Infants born to HBsAg and HBeAg positive mothers have a 70 – 90% chance of acquiring HBV unless they receive hepatitis B vaccine and hepatitis B immunoglobulin (4).

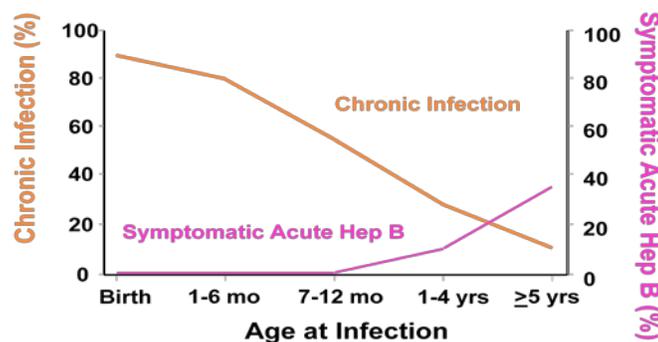
Hepatitis B and Breastfeeding

HBV-positive mothers do NOT need to be separated from their infants nor should their infants be placed in special isolation. HBV-positive mothers can breastfeed their infant unless there is significant breast pathology. Although HBsAg has been detected in some samples of breast milk, special concentration techniques were needed in most studies. In Taiwan, studies revealed that infants breastfed by carrier mothers were no more likely to be infected at 1 year of age than were infants from who breastfeeding was withheld (4).

Age and HBV

There is a direct relationship between age and the likelihood that an acute case will present with symptoms. Infants and children rarely present with jaundice, and frequently will not have any other prodromal symptoms. Approximately 10 – 20% of children over the age of 6 will be symptomatic, and 40 – 50% of adults will present with symptoms (5) (Figure 1.2).

Figure 1.2 Outcome of Hepatitis B Virus Infection by Age at Infection (7)



Risk Factors

There are several groups who are at an increased risk of HBV infection (Figure 1.3). These include (8):

- Infants born to infected mothers
- Persons with multiple sex partners
- Men who have sex with men (MSM)
- Injection drug users (IDU)
- Sexual or household contacts of acutely or chronically infected individuals
- Residents or staff of facilities for developmentally disabled persons
- People undergoing hemodialysis Immigrants/residents of endemic countries
 - Asia
 - Pacific Islands
 - Africa
 - Caribbean
- Areas of South America and the Middle East
- Indigenous populations of Alaska, Australia, and New Zealand. (Figure 1.4)

Figure 1.3 Risk Factors for Hepatitis B (7)

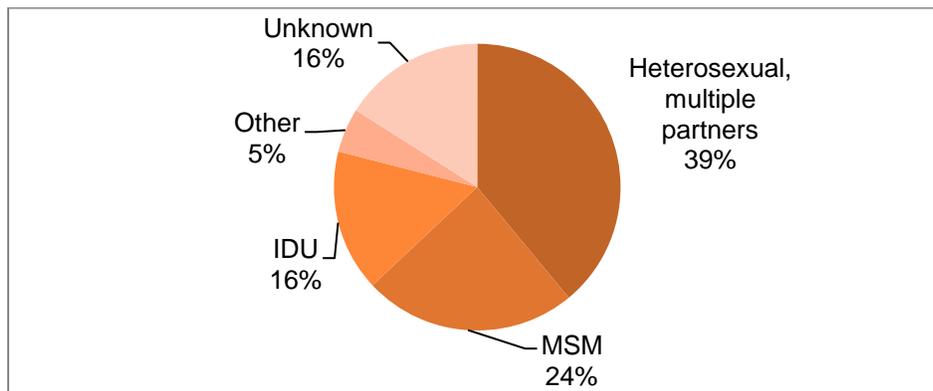
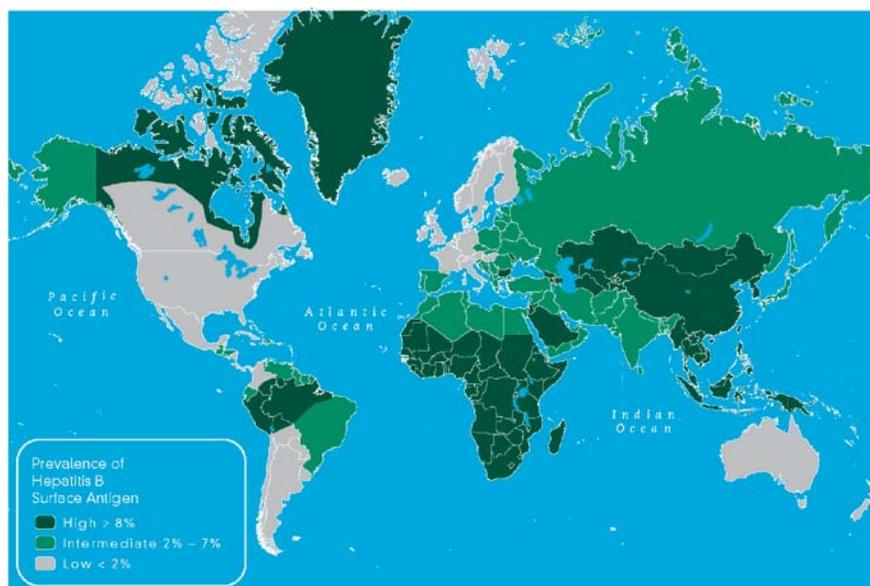


Figure 1.4 Geographic distribution of chronic hepatitis B virus (HBV) infection – worldwide, 2006 (9)



CHAPTER 2: DETECTING AND PREVENTING HEPATITIS B

Diagnosis

Diagnosis of HBV infection is based on clinical and laboratory results and cannot be differentiated from other diseases and conditions based on clinical presentation. Serologic testing involves the measurement of several HBV specific antigens and antibodies which can determine whether an individual has acute or chronic HBV infection or has immunity either from previous vaccination or infection.

Laboratory Tests

Serologic tests have been developed to detect two of the HBV antigens: hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg). Additionally, there are commercial tests available to detect antibodies to hepatitis B surface antigen (anti-HBs), e antigen (anti-HBe), core antigen (anti-HBc), and IgM antibodies to the core antigen (IgM anti-HBc). Tests are also available to quantify HBV DNA in serum (Table 2.1) (4).

Table 2.1 Diagnostic Tests for Hepatitis B Virus (HBV) Antigens and Antibodies (4)

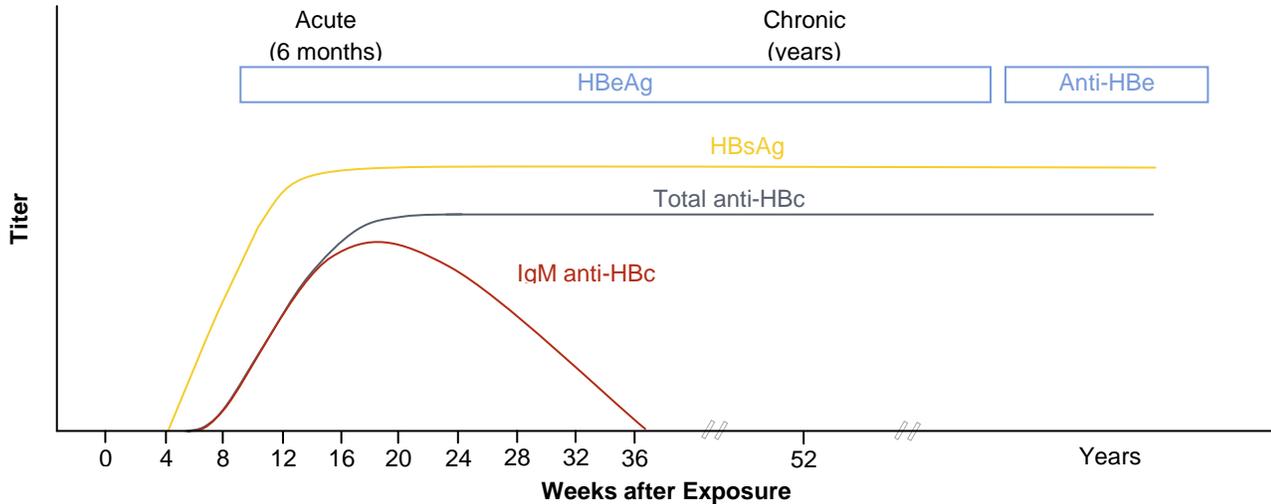
Factor to Be Tested	HBV Antigen or Antibody	Use
HBsAg	Hepatitis B surface antigen	Detection of acutely or chronically infected people; antigen used in hepatitis B vaccine
Anti-HBs	Antibody to HBsAg	Identification of people who have resolved infections with HBV; determination of immunity after immunization
HBeAg	Hepatitis B e antigen	Identification of infected people at increased risk of transmitting HBV
Anti-HBe	Antibody to HBeAg	Identification of infected people with lower risk of transmitting HBV
Anti-HBc	Antibody to HBcAg ¹	Identification of people with acute, resolved, or chronic HBV infection
IgM anti-HBc	IgM antibody to HBcAg	Identification of people with acute or recent HBV infections (including HBsAg-negative people during the “window” phase of infection)

HBcAg indicates hepatitis B core antigen; IgM: immunoglobulin M

¹No test is available commercially to measure HBcAg

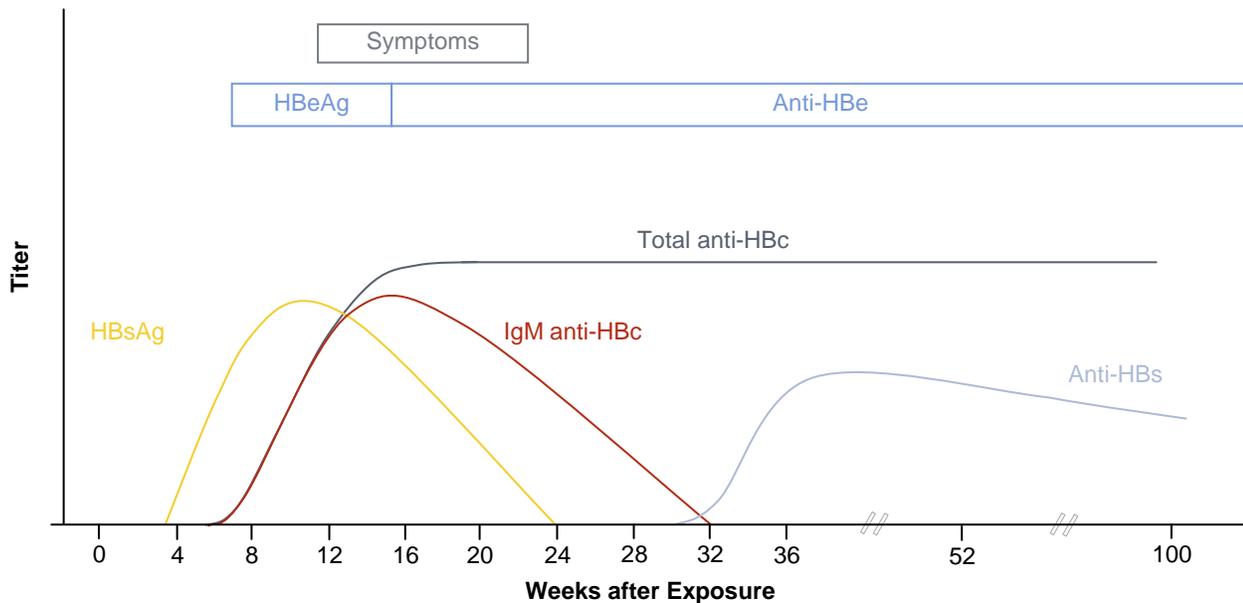
HBsAg is produced in excess during viral replication, and can systemically circulate independently of the virus. Therefore, HBsAg present in the serum is indicative of an active infection. To determine if the infection is acute or chronic, IgM antibody to hepatitis B core antigen (IgM anti-HBc) can be tested; if present, the infection is acute (Figure 2.1). HBsAg can be detected both prior to onset of symptoms as well as several weeks after. During a chronic HBV infection, HBsAg is present continuously in the serum (5).

Figure 2.1 Progression to Chronic Hepatitis B Infection (10)



When a person recovers from an acute HBV infection, antibody to HBsAg (anti-HBs) is produced (Figure 2.2). HBV vaccine, which consists of purified HBsAg, induces the production of anti-HBs. Therefore, the presence of this antibody is an indicator of immunity against HBV, either via natural infection or immunization; antibody titers can be measured for anti-HBs and levels of 10 mIU/mL or greater are considered to be protective. Following an acute HBV infection, anti-HBs levels may not be detectable for several months due to both a delayed rise as well as coupling between HBsAg and anti-HBs (5).

Figure 2.2 Acute Hepatitis B Infection with Recovery (10)



IgM anti-HBc is produced and circulates for the first 3 to 6 months following an acute HBV infection. The presence of antibody to hepatitis B core antigen (anti-HBc) is a marker for past or present HBV infection. This antibody appears shortly after the infection begins and will last throughout a person's life. For this reason, anti-HBc is an excellent marker for a natural infection, as the HBV vaccine does not induce this antibody. Hepatitis B core antigen (HBcAg) is not present outside of the liver during an infection and therefore there are no commercially available tests for this antigen (5). To determine the level of HBV replication, and thus a person's infectivity, a patient can be tested for HBeAg, anti-HBe, or HBV DNA. HBeAg is a soluble antigen that during viral replication is produced in abundance. Therefore, HBeAg positive patients have an increased amount of virus present; conversely, anti-HBe indicates that there are lower levels of HBV

present (Table 2.2). Finally, DNA tests, such as PCR can be performed to detect and quantify the amount of circulating HBV (2).

Table 2.2 Interpretation of the Hepatitis B Serologic Tests (1)

Profile Results		Interpretation	Recommendation*
HBsAg	Negative	Susceptible	Vaccinate
Total anti-HBc	Negative		
anti-HBs	Negative		
HBsAg	Negative	Immune	Vaccination not indicated
Total anti-HBc	Positive or Negative		
anti-HBs	Positive		
HBsAg	Positive	Acutely infected or chronic carrier	Vaccination not indicated
Total anti-HBc	Positive or Negative		
anti-HBs	Negative		
HBsAg	Negative	Multiple interpretations possible, see below. **	Vaccinate (unless patient is recovering from acute infection)
Total anti-HBc	Positive		
anti-HBs	Negative		
HBsAg	Positive	Acutely infected or chronic carrier (presence of HBeAg correlates with higher infectiousness)	Vaccination not indicated
Total anti-HBc	Positive or Negative		
anti-HBs	Negative		
HbeAg	Positive or Negative		
HBsAg	Positive	Acute infection	Vaccination not indicated
Total anti-HBc	Positive		
anti-HBs	Negative		
IgM anti-HBc	Positive		
HBsAg	Negative	Resolving acute infection	Vaccination not indicated
Total anti-HBc	Positive		
anti-HBs	Negative		
IgM anti-HBc	Positive		
HBsAg	Positive	Chronic infection	Vaccination not indicated
Total anti-HBc	Positive		
anti-HBs	Negative		
IgM anti-HBc	Negative		

*Vaccinate according to current ACIP recommendations

**If a person is only positive for anti-HBc while negative for HBsAg and anti-HBs, there are 4 possible explanations.

1. May be recovering from acute HBV infection (vaccination not indicated)
2. May be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum
3. May be undetectable level of HBsAg present in the serum and the person is actually a carrier (acute or chronic).
4. May be susceptible with a false positive anti-HBc

Prevention

A strategy was developed in order to prevent transmission of hepatitis B, which includes (11):

- Prevent perinatal HBV transmission through:
 - Prenatal testing of all pregnant women for HBsAg to identify those newborns who would require immunoprophylaxis for prevention of perinatal infection *and*
 - Identification of household contacts who should be vaccinated
- Routine vaccination of all infants
- Vaccination of adolescents
- Vaccination of adults at high risk for infection

Hepatitis B Immune Globulin

Depending on the exposure circumstance, the hepatitis B vaccine series may be started at the same time as treatment with hepatitis B immune globulin (HBIG) (1).

HBIG is prepared by cold ethanol fraction of plasma from selected donors with high anti-HBs titers; it contains an anti-HBs titer of at least 1:100,000, by radioimmunoassay. It is used for passive immunization for accidental (percutaneous, mucous membrane) exposure, sexual exposure to a hepatitis B positive person, perinatal exposure of an infant, or household exposure of an infant younger than 12 months old to a primary caregiver with acute hepatitis B. Most candidates for HBIG are, by definition, in a high-risk category and should therefore be considered for vaccine as well (1).

HBIG (0.5 mL) should be given intramuscularly (IM), preferably within 12 hours of birth. HBIG given at birth does not interfere with the administration of other vaccines administered at 2 months of age (1).

Hepatitis B Vaccine

For detailed information regarding the hepatitis B vaccine, schedule, and use, please see the chapter pertaining to hepatitis B in CDC's Epidemiology and Prevention of Vaccine Preventable Diseases:

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf>

For further information about specific vaccination procedures for infants born to hepatitis B positive individuals, please refer to Chapter 9, Pediatric Care, of this manual.

Characteristics

Hepatitis B vaccines licensed in the United States are produced by recombinant DNA technology in both single antigen as well as components of combination vaccines. Plasma-derived vaccines were licensed in the United States from 1981 until 1992, but were removed from the market due to unsubstantiated fears of transmission of bloodborne pathogens (e.g. HBV, human immunodeficiency virus); however this type of vaccine is used widely in other countries (4; 1).

Thimerosal, a preservative used in multi-dose vials of vaccine used to prevent contamination, is **no longer present in any of the hepatitis B vaccines that are given to children under the age of 6** (12). Only one hepatitis B combination vaccine (HepA/HepB: Twinrix), which is licensed for use in adults, contains trace amounts of thimerosal (13)

Interchangeability

Antigen content for the various hepatitis B vaccines differs (both in the single antigen as well as the combination vaccine); however, the various brands of hepatitis B vaccines are interchangeable within a vaccine series. The only exception is the two-dose schedule for adolescents aged 11 through 15 years, which is approved only for Recombivax HB (4; 1).

Immunogenicity and Efficacy

Following three intramuscular doses of hepatitis B vaccine, more than 90% of adults and over 95% of infants, children, and adolescents (19 years of age and younger) are protected against HBV infection (Table 2.3) (4; 1) **Error! Reference source not found.** Studies indicate that immunity against HBV infections lasts 15 years or more, even though anti-HBs titers are low or undetectable (4).

Table 2.3: Protection* by Age Group and Dose (1)

Dose	Infants [†]	Teens and Adults [§]
1	16% - 40%	20% - 30%
2	80% - 95%	75% - 80%
3	98% - 100%	90% - 95%

* Anti-HBs antibody titer of 10 mIU/mL

[†] Preterm infants less than 2000 grams have been shown to respond to vaccination less often

[§] Factors that may lower vaccine response rates are age 40 years or older, male gender, smoking, obesity, and immune deficiency

Dosage

The recommended dosage of vaccine depends on both the age of the recipient and the type of vaccine (1).

Route of Administration

Hepatitis B vaccination in adults and children should be administered in the deltoid muscle, while it should be administered in the anterolateral thigh in infants and neonates (1).

Booster Dose

Booster doses are not recommended for healthy adults and children. For hemodialysis and immunocompromised patients at continual risk for hepatitis B, annual serological testing is recommended. A booster dose should be given when the anti-HBs concentration falls below 10 mIU/mL (1).

Vaccination Schedule and Use

Infants and Children

It is recommended that all infants receive hepatitis B vaccination soon after birth and before hospital discharge. Infants and children 11 years and younger should receive 0.5 mL (5µg) of pediatric or adult formulation Recombivax HB (Merck) or 0.5 mL (10 µg) of pediatric Energix-B (GlaxoSmithKline). Primary vaccination consists of three intramuscular doses of vaccine. The typical schedule is 0, 1-2, and 6-18 months. Infants born to hepatitis B positive mothers or to mothers with an unknown hepatitis B status should receive the third (if on the monovalent series) or fourth (if on the Pediarix series) dose at 6 months of age (or 12-15 months of age if Comvax is used), Table 2.4 (1).

Table 2.4: Routine Infant Schedule, Hepatitis B Vaccine (1)

Dose	Usual Age	Minimum Interval
1	Birth	-----
2	1-2 months	4 weeks
3	6-18 months*	8 weeks**

* Infants whose mothers are HBsAg+ or whose HBsAg status is unknown should receive the third dose at 6 months of age

** At least 16 weeks after the first dose

It is preferred that the last two doses of hepatitis B vaccine are spaced at least 4 months apart, as this is when the highest titers of anti-HBs are achieved. However, vaccination schedules with intervals of 2 months between doses (which

conform to schedules of other childhood vaccines), have been shown to produce good antibody responses and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations. However, the **third dose must be administered at least 8 weeks after the second dose, and should follow the first dose by at least 16 weeks. For infants, the third dose should not be given earlier than 24 weeks of age.** It is not necessary to add doses or restart the series if the interval between doses is longer than recommended (1).

Vaccination of preterm infants

Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing <2,000 g, vaccine should be given according to mother's HBsAg status:

- Infants weighing <2,000 g and born to hepatitis B positive mothers should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL).
- Infants weighing <2,000 g and born to mothers whose HBsAg status cannot be determined <12 hours after birth should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL).
 - The birth dose of vaccine for infants born to hepatitis B positive mothers and mothers with unknown HBsAg status should not be counted as part of the 3 doses required to complete the vaccine series; 3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month on the basis of the mother's HBsAg test result
- Infants weighing <2,000 g and born to hepatitis B negative mothers should have their first vaccine dose delayed until 1 month after birth or hospital discharge.

Importance of Hepatitis B Birth dose

The hepatitis B birth dose serves as a "safety net" so that if a mother was improperly diagnosed as hepatitis B negative, and was indeed positive, the infant is still protected at birth. Children born to hepatitis B positive mothers who do not become infected during the perinatal period remain at high risk of infection during early childhood.

The following medical errors may occur, which would prevent clinicians from identifying hepatitis B positive mothers:

- The woman is tested early in pregnancy and found to be hepatitis B negative. She develops HBV infection later in pregnancy but it is not detected. However, it is recommended that high risk women be tested a second time later in pregnancy.
- A chronically infected pregnant woman is tested but with the wrong test, HBsAb (antibody to hepatitis B surface antigen) instead of HBsAg is ordered. This is a common error because the abbreviations for these two tests differ by only one letter. The incorrectly ordered test result is "negative" so her doctor believes her baby does not need prophylaxis.
- The pregnant woman is tested and found to be hepatitis B positive, but her status is not communicated to the newborn nursery.
- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery.

The benefits of administering the first dose of hepatitis B vaccine at birth include:

1. It is the best opportunity to prevent unrecognized perinatal transmission and to prevent horizontal transmission within families due to unrecognized chronic HBV infection in the household.
2. It places the importance of immunization as an early and visible priority for parents.
3. It is the only vaccine that is reliably immunogenic in the newborn period.
4. Administering the vaccine at birth provides opportunity to immunize during one of the few dependable medical encounters (at the delivery hospital). If a mother had little or no prenatal care and comes into the hospital to deliver, chances are these infants will have less medical care than other infants. Therefore, time of delivery provides a good opportunity to immunize these infants.
5. There is added assurance that an overall immunization series will be completed on time; 96.3% of infants complete the vaccine series if given the first dose by age 7 days (14)

It is the foundation of the overall public health strategy to eliminate HBV infection in the United States.

Serologic testing

Pre-vaccination Serologic Testing

Pre-vaccination testing is recommended for all foreign born persons (including immigrants, refugees, asylum seekers, and internationally adopted children) born in Africa, Asia, the Pacific Islands, and other regions with high endemicity of HBV infection (HBsAg prevalence of 8% or higher); **for household, sex, and needle-sharing contacts of hepatitis B positive persons**, and HIV-infected persons. Screening is usually cost-effective, and should be considered for groups with a high risk of HBV infection (prevalence of HBV markers 20% or higher), such as men who have sex with men, injection-drug users, and incarcerated persons. Serologic testing is **not** recommended before routine vaccination of infants and children (1).

Post-vaccination Serologic Testing

Testing for immunity following vaccination is **not routinely** recommended but should be considered for persons whose subsequent management depends on knowledge of their immune status, such as chronic hemodialysis patients, other immunocompromised persons, and persons with HIV infection. Testing is also recommended for sex partners of hepatitis B positive persons. When necessary, post-vaccination testing should be performed 1 to 2 months after completion of the vaccine series (1).

Infants born to hepatitis B positive women should be tested for HBsAg and antibody to HBsAg (anti-HBs) after completion of at least 3 doses of the hepatitis B vaccine series, at age 9 through 18 months. If HBsAg is not present and anti-HBs antibody is present, these infants can be considered to be protected (1).

Vaccine Nonresponse

Several of the factors that have been associated with nonresponse to hepatitis B vaccine are: vaccine factors (e.g., dose schedule, injection site) and host factors (older age, male sex, obesity, smoking, and chronic illness). Further vaccination of persons who fail to respond to a primary vaccination series administered in the deltoid muscle produces adequate response in 15% to 25% of vaccinees after one additional dose and in 30% to 50% after three additional doses (1).

Persons who do not respond to the first series of hepatitis B vaccine should complete a second three-dose vaccine series. The second vaccine series should be given on the usual 0, 1, 6-month schedule. Revaccinated healthcare personnel and others for whom postvaccination serologic testing is recommended should be retested 1 to 2 months after completion of the second vaccine series (1).

Less than 5% of vaccinees do not develop anti-HBs after 6 valid doses of hepatitis B vaccine. They may be a persistent nonresponder or may be a hyporesponder (have a low level of antibody that is not detected by routine serologic testing). One reason a person may be a nonresponder is because the person is HBV positive; therefore, if a person has not responded following 6 doses of HBV vaccine, he or she should be tested for HBsAg. If the uninfected nonresponder is exposed to hepatitis B positive blood he/she should be treated with postexposure prophylaxis (1).

CHAPTER THREE: PERINATAL HEPATITIS B PREVENTION PROGRAM OBJECTIVES

The objectives of the Kansas Department of Health and Environment (KDHE) Perinatal Hepatitis B Prevention program are as follows:

- Establish a mechanism to identify all HBsAg-positive pregnant women
- Conduct case management of all identified infants at risk of acquiring perinatal HBV infection, which includes:
 - Ensuring that the appropriate immunoprophylaxis is administered to all infants born to hepatitis B positive women (including hepatitis B immune globulin [HBIG], hepatitis B vaccine birth dose, and complete vaccine series).
 - Ensuring that post-vaccination serologic testing of all infants born to hepatitis B positive women is completed.
 - That all hepatitis B positive infants are reported to CDC through the Nationally Notifiable Diseases Surveillance System (NNDSS).
- Evaluate the completeness of the identification of hepatitis B positive pregnant women, case management of infants at risk, reporting of hepatitis B positive infants to CDC, and appropriate care of infants born to mothers of with positive or unknown hepatitis B status, based on a methodology provided by CDC.
- Examine the feasibility of developing and implementing a state plan for the universal reporting of maternal hepatitis B test results for all pregnant women.
- Work with hospitals to achieve universal birth-dose coverage and documentation of the birth dose in an immunization information system (IIS).

The program has several important features: 1) it is both a surveillance and control program; 2) it was created using existing data collection systems; 3) it involves both the local and state departments of health; and 4) it uses multiple reporting mechanisms to increase reporting completeness. The surveillance population consists of all pregnant women and their newborn infants. The objectives of the program have evolved with new knowledge on the epidemiology of the disease, but the foundation has proven effective and unchanged. To achieve the objectives of the program KDHE in conjunction with statewide public health partners should focus on the following areas (15):

Ensure that all pregnant women are tested for HBsAg.

- Practitioners should test all pregnant women for HBsAg **during each pregnancy** at their first prenatal visit, even if they have been previously vaccinated or tested;
- HBsAg testing should be incorporated into standard prenatal testing panels (e.g., blood type, HIV infection, Rh factor, rubella titer, syphilis infection) used by all practitioners caring for pregnant women;
- Delivery hospitals should ensure that all pregnant women presenting to their hospital with unknown HBsAg status are immediately tested for HBsAg;
- Women who were found to be HBsAg-negative early in pregnancy and are in a high-risk category (e.g., having had more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually transmitted disease [STD], or recent or current injection-drug use) for acquiring HBV should be retested upon admission to the delivery hospital;
- Hospitals should safeguard against errors in maternal HBsAg testing and failures in test reporting. This can be done by:
 - 1) having standing orders in place for immediate HBsAg testing of all pregnant women for whom there is no copy of a hepatitis B lab result;
 - 2) specifying “HBsAg test” when ordering the test to avoid confusion with other hepatitis B serologic markers;
 - 3) including a copy of the original laboratory HBsAg report in the delivery record;
 - 4) adopting a standing order to give hepatitis B vaccine to all infants, regardless of mother’s hepatitis B status.

Ensure reporting and tracking of hepatitis B positive women.

- All hepatitis B positive pregnant women and all women of childbearing age (women aged 12-55 years) with hepatitis B positive laboratory results must be reported to state/local perinatal hepatitis B prevention programs;
- All hepatitis B positive pregnant women should be entered into the case-management tracking system;
- Reporting of HBsAg test status should be included on hospital-based electronic birth certificates.

Ensure receipt of prenatal HBsAg testing records by maternity hospitals prior to delivery.

- HBsAg test results should be included on all forms (hard copy, electronic) used by practitioners to record and transmit information about care during pregnancy;
- For all pregnant women, a copy of the original laboratory report of HBsAg test results should be transferred from the prenatal care provider to the delivery hospital;
- Practitioners should also document that HBsAg-positive pregnant women have a copy of the original laboratory report, and that patients are informed of their HBsAg test status, educated about the consequences to their newborn, and advised to notify delivery staff.

Ensure identification and management of infants born to hepatitis B positive mothers

- Delivery hospitals should implement policies and procedures to ensure identification of hepatitis B positive women and initiation of post-exposure treatment and immunization of infants born to hepatitis B positive mothers;
- Delivery hospitals should document the date and time of birth, the date and time of administration, the lot number, and manufacturer of hepatitis B immune globulin (HBIG) and hepatitis B vaccine for all infants born to hepatitis B positive mothers;
- Information on administration of any birth doses of vaccine or HBIG should be documented on the infant's electronic birth certificate;
- Information on the mother's hepatitis B status should be documented on the infant's electronic birth certificate.

Ensure identification and management of infants born to mothers without HBsAg test results

- Delivery hospitals should implement policies and procedures to ensure identification and initiation of post-exposure treatment and immunization of infants born to mothers with unknown HBsAg status;
- An infant whose mother's HBsAg test result is positive should immediately receive HBIG (no later than 7 days of age);
- Delivery hospitals should document the date and time of birth, the date and time of administration, the lot number, and manufacturer of HBIG and hepatitis B vaccine, as well as the maternal HBsAg status at time of delivery;
- Information on administration of any birth doses of vaccine or HBIG should be documented on the infant's electronic birth certificate;
- Information on the mother's hepatitis B status should be documented on the infant's electronic birth certificate.

Ensure infant completion of hepatitis B vaccine series.

- The first dose should be given within 12 hours of birth.
- The second dose should be given at one month of age.
- The third dose should be given at six months of age.
- Combination vaccines may be used to complete the series.
- Practitioners should document the dates of completion of each dose of the hepatitis B vaccine series for all infants born to hepatitis B positive mothers.
- Parental consent should be obtained and infant's immunizations should be entered into the Kansas immunization registry, if possible.

Ensure completion of post-vaccination testing.

- Practitioners should document the results of post-vaccination testing after completion of the hepatitis B vaccine series for all infants born to hepatitis B positive mothers;
- HBsAg and anti-HBs testing should be conducted on these infants at 9-18 months of age (1-2 months following last hepatitis B vaccine dose, but not before nine months of age).

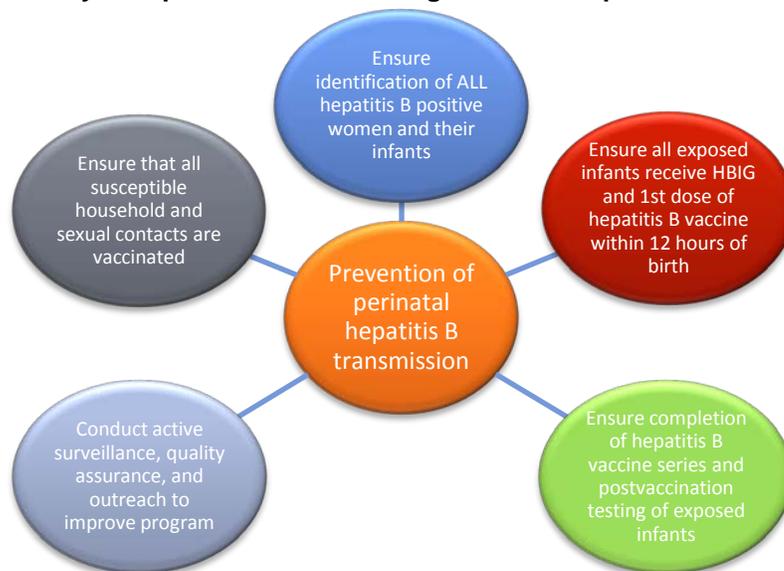
Ensure vaccination of contacts and sex partners of hepatitis B positive women.

- Household contacts, needle-sharing contacts, and sex partners of hepatitis B positive pregnant women should be identified and counseled;
- These contacts should be offered serologic testing and, if susceptible to HBV infection, should receive the hepatitis B vaccine series.

Ensure program quality, monitoring, and evaluation.

- Annually, each program should review the number of pregnant women found to be hepatitis B positive and the proportion of infants born to hepatitis B positive women who received post-exposure prophylaxis within 12 hours of birth, received their third vaccine dose at 6 months of age, and had post-vaccination serologic testing conducted;
- Occasionally, medical errors occur that result in an infant not receiving appropriate prophylaxis. When these errors occur, a case investigation should be conducted by KDHE and local health department staff to identify and document the source of the error.

Figure 3.1 Key Components to Preventing Perinatal Hepatitis B Transmission



CHAPTER FOUR: KANSAS STATE PUBLIC HEALTH LAW

To aid in the identification of hepatitis B positive pregnant women, and thus reduce perinatal hepatitis B transmission, Kansas has provided legislative directives to guide perinatal hepatitis B screening and reporting to protect the residents of Kansas ([Appendix A](#)). It is imperative that legal requirements be shared with health care providers and hospitals to reduce the incidence of transmission of perinatal hepatitis B.

The specific references to perinatal hepatitis B prevention are summarized as follows:

- Providers and hospitals must screen all pregnant women for hepatitis B within 14 days after a diagnosis of pregnancy is made (Kansas Statute Annotated 65-153f)
- Providers and hospitals must report all pregnant hepatitis B positive women (for each pregnancy) within seven days of diagnosis (Kansas Administrative Regulation 28-1-2)

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protects the privacy of medical information, contains specific exceptions that allow covered entities to disclose private health information if required by law [code of federal regulations Title 45, Section 164.512(a)] and to release private health information to a public health authority that is authorized by law to collect and receive information and controlling disease, injury, or disability [Section 164.512(b)].

Reporting Sources

One of the most difficult challenges for a Perinatal Hepatitis B Prevention Program (PHBPP) is obtaining reports of hepatitis B positive pregnant women. To have a successful reporting system, a prevention program should have several overlapping sources of information to identify cases. Four main reporting sources are laboratories, prenatal care providers, delivery hospitals, and birth certificates.

Laboratory Reports

There are several advantages to using laboratory reports as a source of cases:

- Laboratory reporting is more consistent and reliable than provider reporting and is often automatic;
 - Reporting by labs can be made a condition of licensure, but non-laboratory reporting sources require constant reminders and education;
- Because testing is usually done early in the pregnancy, program staff have a long time before the birth of the infant to educate the mother, inform the hospital, and identify and inform a pediatrician;
 - By receiving reports early in the pregnancy, the program staff can begin vaccination of susceptible household and sexual contacts sooner. Later reporting means that the contacts have continuous exposure throughout the pregnancy.

The following are a few examples of problems encountered using laboratory reporting as a source of perinatal cases:

- Sometimes the age and gender identifiers are omitted;
- Prenatal obstetric providers may not order appropriate tests;
- Some women are tested in one state but give birth in another;
- Laboratory reports do not always indicate pregnancy status;
- Some providers do not test at all, test only for members of perceived high-risk groups, or do not test women who were identified as a carrier in a previous pregnancy.

Having alternate reporting sources is a good way to compensate for deficiencies or periodic problems that may occur in laboratory reporting.

Provider Reports

A second reporting source is the prenatal provider (physician, nurse practitioner, certified midwife, etc.). Provider reporting alone should not be used to identify hepatitis B positive pregnant women. A physician can report a hepatitis B positive woman in the following ways:

- Calling program staff at 877-427-7317
- Faxing Prenatal Health Care Provider Report of Hepatitis B Positive Pregnant Women ([Appendix B](#), or http://www.kdheks.gov/epi/disease_reporting.html) to 877-427-7318

If a provider is reluctant to share medical information due to confidentiality issues, explain Section 164.512(b) of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, Kansas Statute Annotated, and Kansas Administrative Regulations that give KDHE authority to conduct disease investigation and gather medical information ([Appendix A](#)).

Health care providers have refused access by public health officials to patient records for immunization assessment and surveillance purposes due to confusion about the intent and implementation of HIPAA. HIPAA allows for all providers, hospitals and laboratories to report hepatitis B positive women to local health agencies without the authorization of the individual. This includes the hepatitis B status of the pregnant woman, serology and vaccine information on the newborn, and household and sexual contacts.

Hospital Reports

Perinatal prevention programs also use hospital reports to identify infants born to hepatitis B positive women. In order to use the hospital as a reporting source, it will be necessary to educate individuals who are responsible for determining a pregnant woman's hepatitis B status and administering HBIG and hepatitis B vaccine to the newborn. Hospital staff designated to identify and report cases should either call in a case report or complete and mail or fax in the case report form (Appendix B).

Birth Certificates

Kansas birth certificates contain a field to document whether the mother had hepatitis B during the pregnancy. This field is not consistently filled out correctly, so is not always a reliable source of information. Local health department staff follows up on all individuals marked as hepatitis B positive on the birth certificate, as indicated by the Perinatal Hepatitis B Prevention Coordinator.

An additional method to identify infants born to hepatitis B positive women is to match individuals who have previously been diagnosed with hepatitis B and are documented in Kansas' online disease surveillance system with mothers who have given birth. The goal of this program is to allow for the identification of hepatitis B positive women that were either not tested during the current pregnancy or whose labs were not reported to KDHE.

Information Transfer

In perinatal hepatitis B prevention programs there are numerous entities to inform of laboratory results and follow up with the mother, infant and contacts (Figure 5.1 and Figure 5.2) in order for the prevention program to succeed.

Figure 5.1: Flow of information, Pre-Delivery Reporting

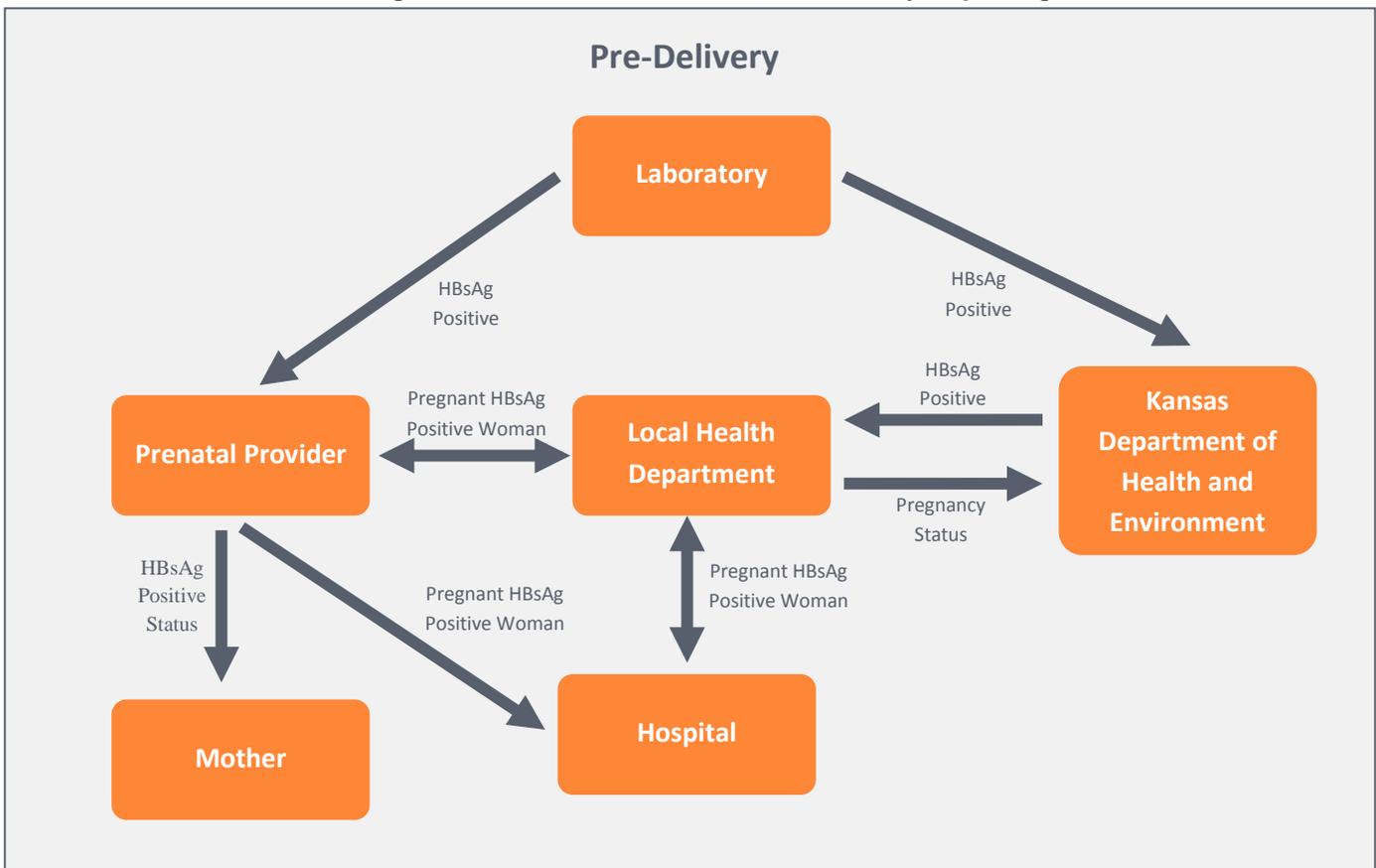
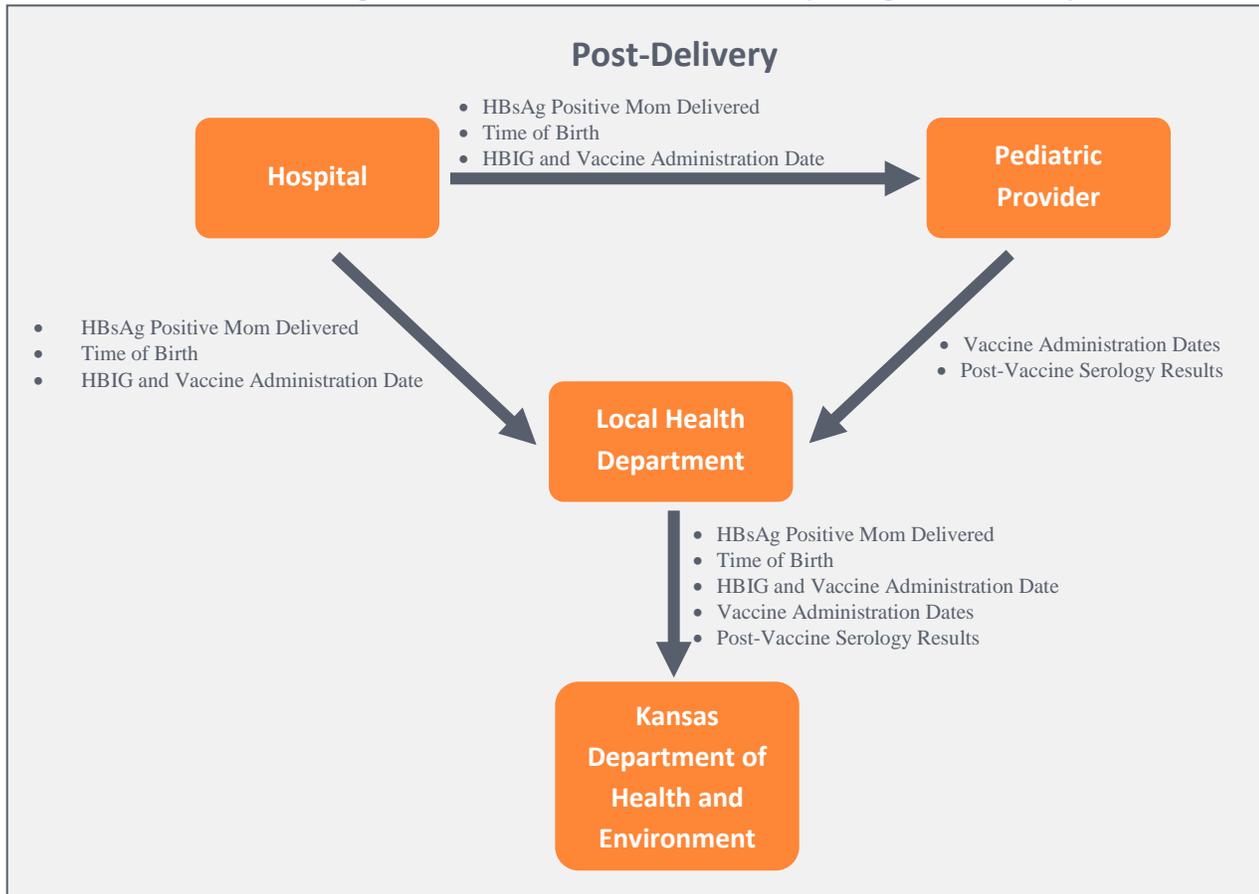


Figure 5.2 Flow of Information and Reporting, Post-Delivery



CHAPTER SIX: ROLE OF LOCAL HEALTH DEPARTMENTS IN CASE MANAGEMENT AND TRACKING

Case management in the Perinatal Hepatitis B Prevention Program involves the following:

- Educating clients on the risks and prevention of disease transmission;
- Notifying the hospital of the mother's hepatitis B status;
- Ensuring infants born to hepatitis B positive mothers receive appropriate prophylaxis at birth;
- Ensuring infants complete the vaccination series and post-vaccination serology (PVS) testing on time;
- Ensuring household and sexual contacts are serologically tested and vaccinated, when necessary;
- Ensuring serologic testing of hepatitis B positive mothers 6 months after first test to determine her carrier status;
- Updating the disease surveillance system, EpiTrax, for hepatitis B positive mothers, their infant(s), household and sexual contacts within 15 days of most updated case management activity.

There are varying degrees of case management, and each case may require different levels of involvement from the local health department (LHD) staff. In one case scenario, the mother may decide to follow-up with her private physician. This is acceptable and should be encouraged. **However, the LHD staff still has the responsibility of gathering all medical information from the provider (dates of vaccine administration and serology test results). This requires little or no contact with the family.** If a family refuses to cooperate with the health department staff, obtain information from their provider, if known. . Prior consent from the mother is not required to obtain vaccine information and serology test results from the provider. If the family refuses all services, document their refusal and your efforts. Some clients may prefer or require more direct services, which may involve home visits to administer vaccines or to draw blood for testing.

The following documentation can also be found here: http://www.kdheks.gov/epi/disease_investigation_guidelines.htm

Case Investigation

The investigation process is dependent on when the local health department was notified of the diagnosis of hepatitis B in a pregnant or post-partum woman.

If Notified During Pregnancy:

- 1) Contact the medical provider who ordered testing of the case and obtain the following information (**Prenatal Care Provider Letter, Appendix D**):
 - Case's demographic data and contact information (birth date, county, sex, race/ethnicity, occupation, address, phone number(s))
 - Estimated date of confinement/estimated date of delivery (EDC/EDD),
 - Expected delivery hospital
 - Insurance status (Private/Medicaid/Uninsured)
- 2) Contact the delivery hospital (**Letter for Hospitals, Appendix D**):
 - Ensure they are aware of the patient's positive HBsAg status and EDC
 - Instruct them to use the Hospital Perinatal Hepatitis B Prevention Reporting Form to report the birth (**Appendix B**). The form is also located at: www.kdheks.gov/epi/download/hepatitis/hosp_rpt_for_perinatal_hep_b.pdf
- 3) Continue with the contact investigation.

If Notified Post-Partum:

- 1) Contact the attending medical provider who ordered testing of the case or the delivery hospital and obtain a copy of the most recent hepatitis B laboratory
- 2) Forward the laboratory results to KDHE
- 3) If the laboratory result is HBsAg negative, no further follow up is needed. Complete and approve the investigation in EpiTrax.
- 4) If laboratory result is positive, continue with the investigation.
 - Manage the case as in Case Management.
 - Investigate contacts as instructed in Contact Investigation.

Contact Investigation

Contacts include: the infant, household members, sexual partners, and needle-sharing contacts.

- 1) Identify the infant's medical provider(s) to allow for follow up with infant's immunizations and post-vaccination serological (PVS) testing as described in Contact Management.
- 2) Obtain the following information from the mother:
 - Names of household members, including the mother's previous children, if any.
 - Names of sexual contacts.
 - Names of needle sharing contacts.
- 3) Review immunization status of contacts and any post-vaccination serologic testing.
- 4) Follow-up with at-risk contacts as instructed in Contact Management.

Note: Contact notification is well-established in the Kansas STD program; the program's specialists have expertise in reaching the types of contacts identified with HBsAg-positive patients and might be able to provide guidance on procedures and best practices. For further assistance, contact the Director or Assistant Director of the Kansas STD Program at (785) 296-5596.

Case Management

- Council on measures to avoid disease transmission, including risks to newborns, and measures to take to protect the liver.
- Educate the mother on immunizations and testing needed for the infant following birth, as described in Contact Management

Contact Management

Both passive-active post-exposure prophylaxis (PEP) with hepatitis B immune globulin (HBIG) and hepatitis B vaccination or active PEP with hepatitis B vaccination alone are highly effective in preventing illness after exposure to HBV. Even though PEP initiated >7 days after percutaneous or >14 days after sexual exposure is not considered an effective means of preventing illness from the initial exposure, the initiation and completion of a hepatitis B vaccination series will protect against future exposures to hepatitis B and is encouraged for all contacts.

For infants born to hepatitis B positive women:

- 1) Notify the infant's pediatrician of the mother's hepatitis B status ([Letter for Pediatric Care Providers, Appendix D](#)), and the steps that need to be taken to prevent the infant from contracting hepatitis B:
 - Within 12 hours of birth: both HBIG (0.5 ml for newborns) and hepatitis B vaccine should be given to infants born to HBsAg-positive mothers (Table 6.1)
 - At 1-2 months: Administer 2nd dose of hepatitis B vaccine
 - At ~6 months: Administer 3rd dose to complete the hepatitis B series.
 - Between 9-18 months of age, at least 1-2 months following last hepatitis B immunization (i.e. at next well child visit): perform post-vaccination serological (PVS) testing for HBsAg and anti-HBs (Table 6.2)
- 2) Obtain these immunization dates and laboratory results of PVS testing from the provider.

Table 6.1 Recommended Schedule for Vaccinating Infants with Monovalent Hepatitis B Vaccine by Mother’s HBsAg Status

Infants Born to HBsAg-Positive Women		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Table 6.2 Post-Vaccination Serologic Testing Results, Interpretation and Resulting Actions Needed

Test Results		Interpretation	Necessary Action
HBsAg	Anti-HBs		
+	-	Infected	<p>The vaccination effort failed. The infant is infected and likely to become a chronic carrier. All confirmed cases of hepatitis B virus infection should be reported to KDHE. Ensure infant receives appropriate follow up care. Services are considered complete.</p> <p>Note: the surveillance case definition for perinatal hepatitis B virus infection is HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother.</p>
-	+	Protected	Services are considered complete.
-	-	Neither infected nor protected	<p>Revaccinate with a second series of hepatitis B vaccine, and retest</p> <ul style="list-style-type: none"> The first dose should be given as soon as possible after post-vaccination serology results are known and follow the 0, 1, 6 month schedule for completing the series. The infant should be retested for HBsAg and anti-HBs, 1-2 months after dose 3 If the child is negative after the second retest, the child should be considered a non-responder. The child is not to receive more than a total of six injections of hepatitis B vaccine.

For contacts of hepatitis B positive women:

- Evaluate each contact’s susceptibility and initiate PEP as soon as possible (preferably within 24 hours). Consider contacts as susceptible if they:
 - Have not completed or initiated their hepatitis B series, and
 - Are without documentation of a prior HBV infection or of a response to a completed hepatitis B series; documentation is indicated by:
 - HBsAg positive laboratory reports (for chronic carriers), or

- Positive report of a protective level of anti-HBs (≥ 10 mIU/mL).
- 2) Unvaccinated past or present sex, household, and needle-sharing contacts should be:
 - Tested for HBsAg and anti-HBs, and at the time of testing:
 - Receive an initial hepatitis B vaccine with or without immune globulin, as recommended in Table 6.3.
 - 3) Contacts determined to be HBsAg-positive are:
 - Reported and managed as hepatitis B cases and referred for medical care.
 - Do not require additional PEP or post vaccination serological testing.
 - 4) Contacts testing positive with a protective level of anti-HBs do not require additional PEP or post vaccination serological testing.
 - 5) Contacts determined to be HBsAg-negative and without a protective level of anti-HBs are provided additional PEP as recommended in Table 6.3.
 - 6) Following completion of the immunization series, susceptible contacts should be tested for anti-HBs and HBsAg 1-2 months following completion of the series
 - If both labs are negative, repeat 3 doses of hepatitis B vaccine and testing 1-2 months following completion
 - 7) Provide education on avoiding further exposures and to ensure proper medical care is obtained and precautions taken if symptoms develop.
 - 8) Report any adverse event that occurs after the administration of a vaccine to Vaccine Adverse Events Reporting System at <http://vaers.hhs.gov/index>.

Table 6.3 Recommended PEP for Uninfected (HBsAg Negative) Contacts Based on Receipt of Hepatitis B Vaccine and Documented Immune Response

Status of Hepatitis B Series and Immune Response	Household Exposure	Initial sexual exposure >14 days prior or initial percutaneous exposure >7 days prior	Initial sexual exposure <14 days prior or initial percutaneous exposure <7 days prior
Unvaccinated (anti-HBs negative)	Administer hepatitis B vaccination series.	Administer hepatitis B vaccination series.	Administer HBIG and hepatitis B vaccination series.
Incomplete series (anti-HBs negative)	Administer remaining doses of Hepatitis B series.	Administer remaining doses of Hepatitis B series.	Administer HBIG and remaining doses of hepatitis B vaccination.
Documented completion of series with no documented immune response or anti-HBs <10.0 mIU/mL	No booster dose needed.	Administer a booster dose of hepatitis B vaccine.	Administer a booster dose of hepatitis B vaccine.
Documented completion of series and anti-HBs ≥ 10.0 mIU/mL:	No booster dose needed.	No booster dose needed.	No booster dose needed.

- If appropriate, HBIG can be administered simultaneously with hepatitis B vaccine in a separate injection site
- For more information, refer to “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States,” <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>.

Education

- 1) Pregnant women should be told about the risk of hepatitis B infection to newborns and of the importance of prophylaxis for infants. Educational materials are available from the CDC and can be found at: <http://www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm>

2) Advise all cases who are HBsAg-positive:

- To notify household, sex, and needle-sharing contacts that they should be tested for markers of HBV infection, vaccinated against hepatitis B, and, if susceptible, complete the vaccine series.
- That the virus may be transmitted through sexual contact and should be instructed to practice abstinence, use condoms, or otherwise practice safe sex until the sex partners are vaccinated and immunity documented.
- Refrain from donating blood, plasma, tissue, or semen (Organs may be donated to HBV-immune or chronically infected persons needing a transplant.);
- Cover cuts or skin lesions to prevent contact with secretions and blood;
- Refrain from sharing household articles (e.g., toothbrushes, razors, or personal injection equipment) that could be contaminated with blood.
- Surfaces contaminated with saliva and blood should be cleaned and properly disinfected, but objects potentially contaminated with blood (e.g., razors, toothbrushes) should not be shared with other people.
- To not share needles with other people.
- When seeking medical or dental care, HBsAg-positive persons should be advised to inform those responsible for their care of their HBsAg status so they can be evaluated and their care managed appropriately.

3) Advise cases on measures to prevent future liver damage.

- Avoid or limit alcohol consumption because of the negative effects of alcohol on the liver;
- Refrain taking any new medicines, including over-the-counter and herbal medicines, without consulting their health-care provider; and
- Obtain vaccination against hepatitis A.

Data Management and Reporting to KDHE

1. On the hepatitis B virus infection, chronic CMR (the mother’s original case), under the clinical tab change pregnant status to “yes” and enter the expected delivery date. Then Save & Continue.

NEW CMR | EVENTS | OUTBREAKS | SEARCH | PEOPLE | PLACES | AVR | SETTINGS | HELP | LOG OUT
ELIZABETH LAWLOR

EDIT MORBIDITY EVENT: HELEN AKUT Save & Continue Save & Exit

PATIENT NAME	DISEASE	JURISDICTIONS	STATUS	EVENT DATE
	Hepatitis B virus infection, chronic	Johnson County Route to Local Health Depts.	Assigned to Local Health Dept. Insufficient privileges to transition this event	2012-03-09

Morbidity Event
Show | Print | Delete | Add Task | Add Attachment | Export to CSV | Create a new event from this one | Events

Pregnancy Status

Pregnant:

Unknown
Yes
No

g clinician

- Then, click “Create a new event from this one”.

- When the options come up, create a “Deep Copy” of the case. Select “Clinical information”, “Labs and lab results”, and “Reporting information”. Then “Create and Edit Deep Copy” .

- In the new CMR that comes up, under Clinical tab, select “Hepatitis B Pregnancy Event” from the disease list. Then select “Save and Continue”.

- Fill out information regarding mom and pregnancy, paying special attention to filling out “insurance type” on the demographics tab and under the administrative tab, the case status will be “Chronic Carrier”.

The image shows two side-by-side screenshots of the EpiTrax web application interface. Both screenshots are for editing a morbidity event for 'HELEN AKUT'. The top navigation bar includes the Kansas Department of Health logo and 'EpiTrax' branding, along with a user profile for 'ELIZABETH LAWLOR'. The main content area is divided into two columns. The left column shows a table with columns for Patient Name, Disease, Jurisdictions, Status, and Event Date. Below the table, there are several dropdown menus for 'Action required' (set to 'Complete'), 'Assign to queue', and 'Assign to investigator'. At the bottom left, under the 'Insurance [Hide]' section, the 'Insurance type' dropdown is set to 'Medicaid', with a blue arrow pointing to it. The right column shows a similar table and dropdowns. At the bottom right, under the 'Case / Outbreak' section, the 'State case status' dropdown is set to 'Chronic Carrier', with a blue arrow pointing to it.

- Under the Contacts tab, add mom’s contacts (including previous children, spouse, etc) – make sure you search for them first. When you are finished adding the basic information for the first contact, click “Add a contact” until you are finished adding all the contacts for this case. When you are finished adding all of the contacts and information on this tab, click “Save & Continue”.

The image shows a screenshot of the TriSano web application interface. The top navigation bar includes the TriSano logo and 'NEW CMR | EVENTS | OUTBREAKS | SEARCH | PEOPLE | PLACES | AVR | SETTINGS | HELP | LOG OUT' for user 'ELIZABETH LAWLOR'. The main content area is for editing a morbidity event for 'HELEN AKUT'. The 'CONTACTS' tab is selected and highlighted in green. Below the tab, the 'Contact Information [Hide]' section is expanded, showing a form with fields for Name, Last name, First name, Disposition, Disposition date, Contact type (set to 'Child by case mother'), and Phone type, Area code, Phone number, and Extension. At the bottom left of the contact information section, there is a red 'Add a contact' button with a red arrow pointing to it.

7. Once you have saved and continued, you will then “edit contact” for each contact of this case.

NEW CMR | EVENTS | OUTBREAKS | SEARCH | PEOPLE | PLACES | AVR | SETTINGS | HELP | LOG OUT
ELIZABETH LAWLOR

EDIT MORBIDITY EVENT: HELEN AKUT [Save & Continue](#) [Save & Exit](#)

PATIENT NAME	DISEASE	JURISDICTIONS	STATUS	EVENT DATE
Morbidity Event	Hepatitis B Pregnancy Event	Unassigned Route to Local Health Depts.	New	2012-03-09

[Show](#) | [Print](#) | [Delete](#) | [Add Task](#) | [Add Attachment](#) | [Export to CSV](#) | [Create a new event from this one](#) | [Events](#)

Name Disposition Disposition date
↑ ↓ Completed March 09, 2012 [Show Contact](#) | [Edit Contact](#)
Phone Contact type Remove
↓ Child by case mother

Name Disposition Disposition date
↑ ↓ Active follow up March 09, 2012 [Show Contact](#) | [Edit Contact](#)
Phone Contact type Remove
↓ Child by case mother

Name Phone Disposition Disposition date
↑ ↓ Active follow up March 09, 2012 [Show Contact](#) | [Edit Contact](#)
Contact type Remove
↓ Spouse sexual contact

[Add a contact](#)

8. Once you select the “Edit Contact”, you must go into the “Investigation” tab and “Add/Remove forms for this event”.

NEW CMR | EVENTS | OUT

EDIT CONTACT EVENT: AWEK DENG

[Show](#) | [Create new contact event](#)

[Disable Tabs]

Demographic Clinical Laboratory **Investigation** Notes

Investigative Information [Hide]

Forms in Use	Forms
Hepatitis B Pregnancy Event Contact Form (core only) v. 1	
Hepatitis B Pregnancy Event Infant Contact Form (core only) v. 1	
Add/Remove forms for this event	

9. Remove the form that you don't need. After you click "remove forms" you'll need to click "Edit Contact" to go back to the Event Screen
 - a. If you are working on the infant that was just born, then remove the "Contact Form"
 - b. If you are working on a contact other than the current infant (previous child, spouse, etc), then remove the "Infant Contact Form".

10. Fill out investigational information, paying particular attention to the "Treatments" under the clinical tab, and the radio buttons under labs, if the patient was screened.

Checklist for Local Health Departments

- CHECK EPITRAX for new (or retested) hepatitis B cases for women ages of 12-55
- INVESTIGATE According to disease investigation protocols:
http://www.kdheks.gov/epi/disease_protocols.htm
- FOLLOW UP with the ordering provider to determine pregnancy status
- ENTER pregnancy status, estimated due date, and expected delivery hospital on the “Clinical” tab in EpiTrax
- CREATE pregnancy event in EpiTrax
- NOTIFY expected delivery hospital of pending delivery for the hepatitis B positive woman
- TEST susceptible household and sexual contacts
- VACCINATE susceptible household and sexual contacts, if needed
- ENSURE baby receives HBIG and first dose of hepatitis B at hospital
- NOTIFY pediatrician of mother’s HBsAg status
- NOTIFY KDHE BEPHI of birth and infant prophylaxis by entering data in EpiTrax
- FAX lab report indicating mother’s HBsAg status to infant’s pediatrician
- ENSURE baby receives second and third doses of vaccine and post serological testing
- UPDATE KDHE BEPHI as baby receives additional doses of hepatitis B and post serological testing via EpiTrax

All Pregnant Women

- All pregnant women need to be tested routinely for hepatitis B surface antigen (**HBsAg**) during an early prenatal visit (e.g., first trimester) in **each** pregnancy, even if they have been previously vaccinated or tested.
 - **Kansas law requires women to be tested for hepatitis B within 14 days of diagnosis of pregnancy (Appendix A, K.S.A. 65-153f).**

Pregnant Women at High Risk for HBV

- Pregnant women who are identified as being at high risk for HBV infection during pregnancy and do NOT have hepatitis B should be vaccinated. High risk behaviors include:
 - Having more than one sex partner during the previous 6 months
 - Been evaluated or treated for an STD
 - Recent or current injection-drug use
 - Having had an hepatitis B positive sex partner
- Pregnant women who are identified as being at high risk for HBV infection during pregnancy or those with clinical hepatitis and who were not vaccinated should be tested at the time of admission to the hospital for delivery.
- Pregnant women at risk for HBV infection during pregnancy should be counseled concerning other methods to prevent HBV infection.

Reporting

- It is Kansas law that all pregnant hepatitis B positive women be reported to KDHE (**Appendix A, K.A.R. 28-1-2**)
- Report all hepatitis B positive pregnant women to the Perinatal Hepatitis B Prevention Program at the Kansas Department of Health and Environment (KDHE) Bureau of Epidemiology and Public Health Informatics (BEPHI) using the **Prenatal Care Provider Report Form (Appendix B)** to ensure that their infants receive timely post-exposure prophylaxis and follow-up.
 - Epidemiology Hotline: 877-427-7317
 - Epidemiology Hotline Fax: 877-427-7318
- A copy of the original laboratory report indicating the pregnant woman's hepatitis B status should be provided to the hospital where delivery is planned
- Prenatal care education should include information regarding the rationale for and importance of newborn hepatitis B vaccination.

Infants of hepatitis B positive mothers may be breastfed beginning immediately after birth.

Check List for Prenatal Care Providers

- TEST all pregnant women for hepatitis B (Hepatitis B Surface Antigen, HBsAg)

- VACCINATE all women who are at high risk for hepatitis B

- REPORT all hepatitis B positive women to KDHE BEPHI using the [Prenatal Care Provider Report Form \(Appendix B\)](#)
 Epidemiology Hotline Phone: 877-427-7317
 Epidemiology Hotline Fax: 877-427-7318

- FAX the lab report indicating the pregnant woman's HBsAg status to planned delivery hospital (regardless of HBsAg status)

- EDUCATE all pregnant women on the rationale and importance of newborn hepatitis B vaccine

Policy Recommendations

The Advisory Committee on Immunization Practices (ACIP) has published a series of recommendations for delivery hospitals to prevent perinatal hepatitis B transmission (Figure 8.1) (11).

Figure 8.1 ACIP recommendations for delivery hospitals to prevent perinatal HBV transmission (11)

<p>At time of admission for delivery</p> <ul style="list-style-type: none">• Review hepatitis B surface antigen (HBsAg) status of all pregnant women• Record maternal HBsAg test results on both labor and delivery record and on infant’s delivery summary sheet• Perform HBsAg testing as soon as possible on women who<ul style="list-style-type: none">○ Do not have a documented HBsAg test result○ Were at risk for HBV infection during pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or hepatitis B positive sex partner), or○ Had clinical hepatitis since previous testing <p>After delivery</p> <p><i>Hepatitis B positive mothers and their infants</i></p> <ul style="list-style-type: none">• Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants born to Hepatitis B positive mothers ≤ 12 hours after birth, and record date and time of administration of HBIG and hepatitis B vaccine in infant’s medical record.• Provide information regarding hepatitis B to Hepatitis B positive mothers, including<ul style="list-style-type: none">○ Advice that they may breast feed their infants upon delivery;○ Modes of HBV transmission;○ Need for vaccination of their susceptible household, sexual, and needle-sharing contacts;○ Need for substance abuse treatment, if appropriate; and○ Need for medical management and possible treatment for chronic hepatitis B <p><i>Mothers with unknown HBsAg status and their infants</i></p> <ul style="list-style-type: none">• Administer single-antigen hepatitis B vaccine (without HBIG) to all infants born to mothers with unknown HBsAg status ≤ 12 hours after birth and record date and time of administration of hepatitis B vaccine on infant’s medical record• Alert infant’s pediatric health-care provider if an infant is discharged before the mother’s HBsAg test result is available; if the mother is determined to be HBsAg positive, HBIG should be administered to the infant as soon as possible, but no later than age 7 days <p><i>All mothers and their infants</i></p> <ul style="list-style-type: none">• Administer a dose of single-antigen hepatitis B vaccine to all infants weighing $\geq 2,000$ g• Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results <p>At time infant is discharged</p> <ul style="list-style-type: none">• Provide infant’s immunization record to mother and remind her to take it to the infant’s first visit to a pediatric
--

Identification and Testing

- Check hepatitis B lab reports for **each** woman admitted to labor and delivery
- Women who **were not screened prenatally** for hepatitis B **or with no documentation of hepatitis B test results** should be tested at the time of admission to the hospital for delivery.
- Women who engage in behaviors that put them at high risk for hepatitis B and those with clinical hepatitis should be tested as soon as possible at the time of admission to the hospital for delivery. High risk behaviors include:
 - Injection-drug use
 - Having had more than one sex partner in the previous 6 months
 - A hepatitis B positive sex partner
 - Evaluation or treatment for a sexually transmitted disease [STD]
 - Recent or current injection-drug use

Documentation

- A copy of the original laboratory report indicating the pregnant woman's hepatitis B status should be provided to the hospital where delivery is planned and to the health-care provider who will care for the newborn.
- Documentation of maternal HBsAg test results should be in all infant medical records (regardless of hepatitis B status)
 - ACIP recommends including a **copy of the maternal lab** results in the infant chart

Reporting

- KDHE BEPHI Perinatal Hepatitis B Prevention Program are to be notified of women who are hepatitis B positive to ensure that their infants receive the follow-up doses of vaccine and post serologic testing, per K.A.R. 28-1-2 (Appendix A). Hospitals can use the [Hospital Report Form \(Appendix B\)](#) to report to KDHE.
 - Epidemiology Hotline Phone: 877-427-7317
 - Epidemiology Hotline Fax: 877-427-7318

Prophylaxis of Infants

Delivery hospitals not already enrolled in the federally funded Vaccines for Children (VFC) program should consider enrolling in order to obtain free hepatitis B vaccine for administration of the birth dose to all newborns.

For information about VFC, please contact the Kansas Immunization Program (785) 296-5591.

All infants

- All delivery hospitals should implement standing orders for administration of hepatitis B vaccination before hospital discharge as part of routine medical care of all medically stable infants weighing $\geq 2,000$ grams at birth.
 - On a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs $\geq 2,000$ grams and whose mother is hepatitis B negative.
 - When such a decision is made, a physician's order to withhold the birth dose and a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record.
 - For infants who do not receive the first dose before hospital discharge, the first dose should be administered no later than age 2 months.
 - Situations in which the birth dose should not be delayed include any high-risk sexual or drug-using practices of the infant's mother during pregnancy (e.g., having had more than one sex partner during the previous 6 months or an hepatitis B positive sex partner, evaluation or treatment for an STD, or recent or current injection-drug use) and expected poor compliance with follow-up to initiate the vaccine series.
- All infants should receive the first dose hepatitis B vaccine series within 12 hours of birth as part of the recommended childhood immunization schedule (Table 8.1).

Table 8.1 Hepatitis B immunization management of infants born to hepatitis B negative women (11)

Biologic	Dose	Age of Infant
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth
Hepatitis B Vaccine-dose 2	0.5 mL	1-2 months
Hepatitis B Vaccine-dose 3	0.5 mL	6-18 months**

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Infants born to hepatitis B positive mothers

- Prepare for upcoming births to mothers who are hepatitis B positive by having HBIG on hand and policies in place to give HBIG and the first dose of hepatitis B vaccine within 12 hours of birth.
- All infants born to hepatitis B positive women should receive single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth, administered at different injection sites (Table 8.2).

Table 8.2 Hepatitis B immunization management of infants born to hepatitis B positive women (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Infants born to mothers with unknown hepatitis B status

- While test results are pending, all infants born to women without documentation of hepatitis B test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth (Table 8.3).
 - If the mother is determined to be hepatitis B positive, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a recommended schedule for infants born to hepatitis B positive mothers.
 - If the mother is determined to be hepatitis B negative, the vaccine series should be completed according to a recommended schedule for infants born to hepatitis B negative mothers.
- When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine within 12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to hepatitis B positive mothers. Administration of HBIG is not necessary for these infants (11).
 - Hospitals should develop procedures that allow for obtaining HBsAg test results within 24 hours

Table 8.3 Hepatitis B immunization management of infants born to women with unknown hepatitis B status (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	If mother is postnatally found to be hepatitis B positive, administer HBIG to infant as soon as possible, but no later than 7 days of birth
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 (given at approximately 1 month of age) and dose 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Preterm infants

- Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing <2,000 g, all delivery hospitals should implement policies and procedures for management of infants weighing <2,000 g at birth, including the following:
 - Infants weighing <2,000 g and born to **hepatitis B positive mothers** should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL) <12 hours after birth (Table 8.4).
 - Infants weighing <2,000 g and born to mothers whose **HBsAg status cannot be determined** should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL) <12 hours after birth (Table 8.5).
 - Infants weighing <2,000 g and born to **hepatitis B negative** mothers should have their first vaccine dose delayed until 1 month after birth or hospital discharge. For these infants, a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record (Table 8.6).
 - The birth dose of hepatitis B vaccine for infants born to hepatitis B positive mothers and mothers with unknown HBsAg status should not be counted as part of the 3 doses required to complete the vaccine series; **3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month on the basis of the mother's HBsAg test result.**

Table 8.4 Hepatitis B immunization management of preterm infants born to hepatitis B positive women (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-birth dose	0.5 mL	Within 12 hours of birth* (Do not count birth dose as part of the vaccine series)
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 (given at approximately 1 month of age) and dose 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Table 8.5 Hepatitis B immunization management of preterm infants born to women with unknown hepatitis B status (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-birth dose	0.5 mL	Within 12 hours of birth* (Do not count birth dose as part of the vaccine series)
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Table 8.6 Hepatitis B immunization management of preterm infants born to hepatitis B negative women (11)

Biologic	Dose	Age of Infant
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 months
Hepatitis B Vaccine-dose 3	0.5 mL	6-18 months**

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Education

- Pre- and post-natal care education should include information regarding the rationale for and importance of newborn hepatitis B vaccination.
- Infants of hepatitis B positive mothers may be breastfed beginning immediately after birth.

Checklist for Hospitals

- PREPARE for upcoming births to HBsAg positive mothers
- CHECK HBsAg lab report for each woman entering labor & delivery
- TEST all women with unknown HBsAg status at time of admission for delivery
- RETEST all women who engage in high risk factors during pregnancy
- EDUCATE new mothers on the importance of newborn hepatitis B vaccine
- KEEP A COPY of the lab results with HBsAg status in mother's chart
- PUT A COPY of the mother's HBsAg lab results in all infant medical records
- VACCINATE all infants weighing $\geq 2,000\text{g}$ with the first dose of hepatitis B vaccine within 12 hours of birth
- ADMINISTER single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth at different injection sites for all infants born to hepatitis B positive women
- REPORT all women who are HBsAg positive to your local health department or the KDHE BEPHI perinatal hepatitis B program using the [Hospital Report Form, Appendix B](#)
Epidemiology Hotline Phone: 877-427-7317
Epidemiology Hotline Fax: 877-427-7318
- ENROLL delivery hospitals should enroll in the federally funded Vaccines for Children (VFC) program, if not already a participant

Identification and Management

- Obtain maternal HBsAg test result from the delivery hospital laboratory and provide appropriate management on the basis of those results:
 - If the mother is HBsAg positive, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a schedule for infants born to HBsAg-positive mothers
 - If the mother is HBsAg negative, the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-negative mothers.
 - If the mother does not have a recorded HBsAg result, request she be tested as soon as possible to determine appropriate management course.

Vaccination

Infants born to hepatitis B positive mothers

- Prepare for upcoming births to mothers who are hepatitis B positive by having HBIG on hand and policies in place to give HBIG and the first dose of hepatitis B vaccine within 12 hours of birth
- All infants born to hepatitis B positive women should receive single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth, administered at different injection sites (Table 9.1).
- The typical schedule is 0, 1-2, and 6-18 months.
 - Infants born to hepatitis B positive mothers or hepatitis B unknown mothers should receive the third (if on the monovalent series) or fourth (if on the Pediarix series) dose at 6 months of age (or 12-15 months of age if Comvax is used) (1).
- It is preferred that the last two doses of hepatitis B vaccine are spaced at least 4 months apart, as this is when the highest titers of anti-HBs are achieved.
 - However, vaccination schedules with intervals of 2 months between doses (which conform to schedules of other childhood vaccines), have been shown to produce good antibody responses and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations.
- **The third dose must be administered at least 8 weeks after the second dose, and should follow the first dose by at least 16 weeks. For infants, the third dose should not be given earlier than 24 weeks of age.**
- It is not necessary to add doses or restart the series if the interval between doses is longer than recommended (1).

Table 9.1 Hepatitis B immunization management of infants born to hepatitis B positive women Invalid source specified.

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Infants born to mothers with unknown hepatitis B status

- While test results are pending, all infants born to women without documentation of hepatitis B test results should receive the first dose of single-antigen hepatitis B vaccine (without HBIG) within 12 hours of birth (Table 9.2).
 - If the mother is determined to be hepatitis B positive, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a recommended schedule for infants born to hepatitis B positive mothers.
 - If the mother is determined to be hepatitis B negative, the vaccine series should be completed according to a recommended schedule for infants born to hepatitis B negative mothers.
- When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine within 12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to hepatitis B positive mothers. Administration of HBIG is not necessary for these infants (11).
 - Hospitals should develop procedures that allow for obtaining HBsAg test results within 24 hours
- The typical schedule is 0, 1-2, and 6-18 months.
 - Infants born to hepatitis B positive mothers or hepatitis B unknown mothers should receive the third (if on the monovalent series) or fourth (if on the Pediarix series) dose at 6 months of age (or 12-15 months of age if Comvax is used) (1).
- It is preferred that the last two doses of hepatitis B vaccine are spaced at least 4 months apart, as this is when the highest titers of anti-HBs are achieved.
 - However, vaccination schedules with intervals of 2 months between doses (which conform to schedules of other childhood vaccines), have been shown to produce good antibody responses and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations.
- **The third dose must be administered at least 8 weeks after the second dose, and should follow the first dose by at least 16 weeks. For infants, the third dose should not be given earlier than 24 weeks of age.**
- It is not necessary to add doses or restart the series if the interval between doses is longer than recommended (1).

Table 9.2 Hepatitis B immunization management of infants born to women with unknown hepatitis status (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	If mother is postnatally found to be hepatitis B positive, administer HBIG to infant as soon as possible, but no later than 7 days of birth
Hepatitis B Vaccine-dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-dose 2	0.5 mL	1 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The first dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Preterm infants

- Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing <2,000 g, all delivery hospitals should implement policies and procedures for management of infants weighing <2,000 g at birth, including the following:
 - Infants weighing <2,000 g and born to **hepatitis B positive mothers** should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL) (Table 9.3).

- Infants weighing <2,000 g and born to mothers whose **HBsAg status cannot be determined** <12 hours after birth should receive both single-antigen hepatitis B vaccine and HBIG (0.5 mL) (Table 9.4).
- Infants weighing <2,000 g and born to **hepatitis B negative** mothers should have their first vaccine dose delayed until 1 month after birth or hospital discharge. For these infants, a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record (Table 9.5).
- The birth dose of hepatitis B vaccine for infants born to hepatitis B positive mothers and mothers with unknown HBsAg status should not be counted as part of the 3 doses required to complete the vaccine series; **3 additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month on the basis of the mother's HBsAg test result.**

Table 9.3 Hepatitis B immunization management of preterm infants born to hepatitis B positive women (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-birth dose	0.5 mL	Within 12 hours of birth* (Do not count birth dose as part of the vaccine series)
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The birth dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 (given at approximately 1 month of age) and dose 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Table 9.4 Hepatitis B immunization management of preterm infants born to women with unknown hepatitis status (11)

Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine-birth dose	0.5 mL	Within 12 hours of birth* (Do not count birth dose as part of the vaccine series)
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 month
Hepatitis B Vaccine-dose 3	0.5 mL	6 months**

* The birth dose of vaccine should be given at the same time as HBIG but at a separate site. The preferred sites are the anterolateral thighs. If necessary, HBIG can be administered up to 7 days after birth.

** The minimum interval between dose 1 (given at approximately 1 month of age) and dose 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Table 9.5 Hepatitis B immunization management of preterm infants born to hepatitis B negative women (11)

Biologic	Dose	Age of Infant
Hepatitis B Vaccine-dose 1	0.5 mL	1 month
Hepatitis B Vaccine-dose 2	0.5 mL	2 months
Hepatitis B Vaccine-dose 3	0.5 mL	6-18 months**

** The minimum interval between dose 1 and 3 is 4 months. Infant should not receive the third dose of HB vaccine prior to 6 months of age.

Post-vaccination serological testing (PVS) for Infants born to hepatitis B positive women

- Post-vaccination testing for anti-HBs and HBsAg should be performed after completion of the vaccine series, at age 9-18 months, approximately 1-2 months after the third dose (generally at the next well-child visit). Testing **should not be performed before age 9 months of age** to avoid detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc might be detected in infants born to HBV-infected mothers to age 24 months (Table 9.6).
 - HBsAg-negative infants with positive anti-HBs levels (>10 mIU/mL) are protected and need no further medical management.
 - HBsAg-negative infants with negative anti-HBs levels (<10 mIU/mL) should be revaccinated with a second 3-dose series and retested 1-2 months after the final dose of vaccine.
 - If the child is negative after the second retest, the child should be considered a non-responder. The child is not to receive more than a total of six injections of hepatitis B vaccine.
 - Infants who are HBsAg positive should receive appropriate follow-up:
 - If the infant is HBsAg positive in another 6 months the infant has become a chronic carrier of hepatitis B

Reporting

- Report all vaccination dates and post-vaccination serological testing to KDHE using the [Pediatric Care Report Form \(Appendix B\)](#)
- Report all perinatal hepatitis B infections to the Kansas Department of Health and Environment (KDHE) Bureau of Epidemiology and Public Health Informatics (BEPHI) using the [Notifiable Disease Form \(Appendix C\)](#)
 - Epidemiology Hotline Phone: 877-427-7317
 - Epidemiology Hotline Fax: 877-427-7318

Table 9.6 Post-Vaccination Serologic Testing Results, Interpretation and Resulting Actions Needed (1)

Test Results		Interpretation	Necessary Action
HBsAg	Anti-HBs		
+	- (<10 mIU/mL)	Infected	<p>The vaccination effort failed. The infant is infected and likely to become a chronic carrier. All confirmed cases of hepatitis B virus infection should be reported to KDHE. Ensure infant receives appropriate follow up care. Services are considered complete.</p> <p>Note: the surveillance case definition for perinatal hepatitis B virus infection is HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother.</p>
-	+ (>10 mIU/mL)	Protected	Services are considered complete.
-	- (<10 mIU/mL)	Neither infected nor protected	<p>Revaccinate with a second series of hepatitis B vaccine, and retest</p> <ul style="list-style-type: none"> • The first dose should be given as soon as possible after post-vaccination serology results are known and follow the 0, 1, 6 month schedule for completing the series. The infant should be retested for HBsAg and anti-HBs, 1-2 months after dose 3 • If the child is negative after the second retest, the child should be considered a non-responder. The child is not to receive more than a total of six injections of hepatitis B vaccine.

Checklist for Pediatric Care Providers

- ENSURE all infants complete the hepatitis B vaccination series on time
- PERFORM post-vaccination testing (HBsAg and anti-HBs) for infants born to hepatitis B positive mothers after completion of the vaccine series, at age 9--18 months, approximately 3-6 months after the 3rd dose (typically at next well-child visit)
 - HBsAg-negative infants with anti-HBs levels >10 mIU/mL are protected
 - Revaccinate infants who are HBsAg-negative and with anti-HBs levels <10 mIU/mL with a second 3-dose series and retest 1--2 months after the final dose of vaccine.
 - Infants who are HBsAg positive should receive appropriate follow up
- REPORT all vaccination dates and post-vaccination serological testing to KDHE BEPHI Perinatal Hepatitis B Prevention Program using the [Pediatric Care Report Form \(Appendix B\)](#)
Epidemiology Hotline Phone: 877-427-7317
Epidemiology Hotline Fax: 877-427-7318
- REPORT all perinatal infections to the KDHE BEPHI Perinatal Hepatitis B Prevention Program using the [Notifiable Disease Form \(Appendix C\)](#)
Epidemiology Hotline Phone: 877-427-7317
Epidemiology Hotline Fax: 877-427-7318

REFERENCES

1. **Centers for Disease Control and Prevention.** Epidemiology and Prevention of Vaccine-Preventable Diseases. [ed.] William Atkinson, et al. 11th. Washington DC : Public Health Foundation, 2009.
2. **Murray, Patrick R, et al., [ed.].** *Manual of Clinical Microbiology.* 8th. Washington DC : ASM Press, 2003. Vol. 2.
3. **American Public Health Association.** *Control of Communicable Diseases Manual.* Baltimore, MD : United Book Press, Inc, 2008.
4. **American Academy of Pediatrics.** *Red Book: 2006 Report of the Committee on Infectious Diseases.* [ed.] Larry K Pickering, et al. 27th. Elk Grove, IL : American Academy of Pediatrics, 2006.
5. **Nelson, Kenrad E and Williams, Carolyn Masters.** *Infectious Disease Epidemiology: Theory and Practice.* 2nd. Sudbury, MA : Jones and Bartlett Publishers, 2007.
6. **World Health Organization.** Hepatitis B Fact Sheet. *World Health Organization.* [Online] 2008. [Cited: January 27, 2011.] <http://www.who.int/mediacentre/factsheets/fs204/en/>.
7. **Ward, John and Prevention, Centers for Disease Control and.** Hepatitis A Through E: An Overview. *University of Alabama at Birmingham.* [Online] 2007. www.microbio.uab.edu/medmicro/lectures/ward.ppt.
8. **Centers for Disease Control and Prevention.** Recommendations of the Advisory Committee on Immunization Practices (ACIP). A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Immunization of Adults. *MMWR.* 2006, Vol. 55, RR-16.
9. **Centers for Disease Control and Prevention.** *CDC Health Information for International Travel 2012.* Atlanta : U.S. Department of Health and Human Services, Public Health Service, 2012.
10. **Centers for Disease Control and Prevention.** CDC Division of Viral Hepatitis Online Serology Training. [Online] 2008. http://www.cdc.gov/hepatitis/Resources/Professionals/Training/Serology/gr_hbv_chronic.htm.
11. **Centers for Disease Control and Prevention.** Recommendations of the Advisory Committee on Immunization Practices (ACIP). A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Immunization of Infants, Children, and Adolescents. *MMWR.* 2005, Vol. 54, RR16.
12. **Centers for Disease Control and Prevention.** Thimerosal FAQs - Vaccine Safety. [Online] 2009. http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html#1.
13. **U.S. Food and Drug Administration.** Vaccines, Blood, and Biologicals: Thimerosal in Vaccines. [Online] 2009. <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/vaccinesafety/ucm096228>.
14. **Yusuf, Hussain, et al.** Association Between Administration of Hepatitis B Vaccine at Birth and Completion of the Hepatitis B and 4:3:1:3 Vaccine Series. *The Journal of the American Medical Association.* 2000, Vol. 284, 8.
15. **Centers for Disease Control and Prevention.** Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen. *MMWR.* 1988, Vol. 37, 22.
16. **Willis, Bayo, et al.** Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus. *Pediatrics.* 2010, Vol. 125, 4.
17. **Wasley, Annemarie, et al.** The Prevalence of Hepatitis B Virus Infection in the United States in the Era of Vaccination. *Journal of Infectious Diseases.* 2010, Vol. 202, 2, pp. 192-201.
18. **Stevens, CE, et al.** *Perinatal hepatitis B virus transmission in the United States. Prevention by passive-active immunization.* 12, March 22-29, 1985, JAMA, Vol. 253, pp. 1740-5.
19. **R Palmer Beasley, George Chin-Yun Lee, Cheng-Hsiung Roan, Lu-Yu Hwang, Chung-Chi Lan, Fu-Yuan Huang, Chiung-Lin Chen.** *Prevention of Perinatally Transmitted Hepatitis B Virus Infections with Hepatitis B Immune Globulin and Hepatitis B Vaccine.* 8359, November 12, 1983, The Lancet, Vol. 332, pp. 1099-1102.
20. **O'Leary, Sean, Nelson, Christina and Duran, Julie.** Maternal Characteristics and Hospital Policies as Risk Factors for Nonreceipt of Hepatitis B Vaccine in the Newborn Nursery. *The Pediatric Infectious Disease Journal.* 2012, Vol. 31, 1.

21. **Centers for Disease Control and Prevention.** Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine. *MMWR*. 1982, Vol. 31, 24.
22. **Anderson, Teresa and Wexler, Deborah.** *States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention*. s.l. : Immunization Action Coalition, 2012.
23. **Centers for Disease Control and Prevention.** Viral Hepatitis Statistics & Surveillance. *Centers for Disease Control and Prevention*. [Online] November 15, 2010. [Cited: 01 27, 2011.] <http://www.cdc.gov/hepatitis/Statistics/index.htm>.
24. **Kansas Department of Health and Environment, Bureau of Epidemiology and Disease Prevention.** Reportable Diseases in Kansas, 2006 Summary. [Online] 2006. http://www.kdheks.gov/epi/download/disease_summary/dissum06.pdf.
25. **Centers for Disease Control and Prevention.** Prevention of Perinatal Group B Streptococcal Disease. *MMWR*. 2002, Vol. 51, RR11.
26. **Centers for Disease Control and Prevention.** Mother-to-Child (Perinatal) HIV Transmission and Prevention. *CDC HIV/AIDS Fact Sheet*. [Online] CDC , October 2007. <http://www.cdc.gov/hiv/topics/perinatal/resources/factsheets/perinatal.htm>.
27. **Centers for Disease Control and Prevention.** *Managing a Perinatal Hepatitis B Prevention Program: A Guide to Life*. Atlanta : s.n.
28. **Kansas Department of Health and Environment.** *Kansas Annual Summary of Vital Statistics, 2011*. 2012.
29. **Centers for Disease Control and Prevention.** Hepatitis B FAQs for the Public. *Centers for Disease Control and Prevention*. [Online] June 9 2009. <http://www.cdc.gov/hepatitis/b/bfaq.htm>.
30. **European Consensus Group on Hepatitis B Immunity.** Are booster immunisations needed for lifelong hepatitis B immunity? *Lancet*. 2000, Vol. 355, 561-65.

APPENDICES
TABLE OF CONTENTS

APPENDIX A – LAWS47

APPENDIX B – REPORTING FORMS.....51

PRENATAL CARE PROVIDER REPORT FORM.....52

HOSPITAL REPORT FORM53

PEDIATRIC PROVIDER REPORT FORM54

APPENDIX C – KANSAS NOTIFIABLE DISEASE FORM55

APPENDIX D – LETTERS FOR PROVIDERS56

LETTER FOR PRENATAL CARE PROVIDERS57

LETTER FOR PEDIATRIC CARE PROVIDERS, PRE-DELIVERY58

LETTER FOR PEDIATRIC CARE PROVIDERS, POST-DELIVERY59

LETTER FOR HOSPITALS60

APPENDIX E – ADDITIONAL RESOURCES61

APPENDIX A

LAWS

Kansas Statute Annotated (K.S.A) 65-153f

Chapter 65 -- Public Health

Article 1 -- Secretary of Health and Environment, Activities

65-153f. Prenatal serological tests for syphilis and hepatitis b; approved laboratories; laboratory reports, confidentiality. Each physician or other person attending a pregnant woman in this state during gestation, with the consent of such woman, shall take or cause to be taken a sample of blood of such woman within 14 days after diagnosis of pregnancy is made. Such sample shall be submitted for serological tests which meet the standards recognized by the United States public health service for the detection of syphilis and hepatitis b to a laboratory approved by the secretary of health and environment for such serological tests. Any state, United States public health service, or United States army, navy or air force laboratory or any laboratory approved by the state health agency of the state in which the laboratory is operated shall be considered approved for the purposes of this act. Any laboratory in this state, performing the tests required by this section shall make a report to the secretary of health and environment of all positive or reactive tests on forms provided by the secretary of health and environment and also shall make a report of the test results to the submitting physician or person attending the woman. Laboratory statements, reports, files and records prepared pursuant to this section shall be confidential and shall not be divulged to or open to inspection by any person other than state or local health officers or their duly authorized representatives, except by written consent of the woman.

Kansas Administrative Regulation (K.A.R) 28-1-2

Agency 28 -- Department of Health and Environment

Article 1 – Diseases

28-1-2. Designation of infectious or contagious diseases.

- (a) The following diseases shall be designated as infectious or contagious in their nature, and cases or suspect cases shall be reported within seven days, unless otherwise specified, in accordance with K.S.A. 65-118 and K.S.A. 65-128, and amendments thereto.
- (1) Amebiasis;
 - (2) anthrax (report by telephone within four hours to the secretary);
 - (3) arboviral disease, including WestNile virus, western equine encephalitis (WEE), and St. Louis encephalitis (SLE);
 - (4) botulism (report by telephone within four hours to the secretary);
 - (5) brucellosis;
 - (6) campylobacter infections;
 - (7) chancroid;
 - (8) Chlamydia trachomatis genital infection;
 - (9) cholera (report by telephone within four hours to the secretary);
 - (10) cryptosporidiosis;
 - (11) cyclospora infection;
 - (12) diphtheria;
 - (13) ehrlichiosis;
 - (14) Escherichia coli enteric infection from E. coli O157:H7 and other shiga toxin-producing E. coli, also known as STEC;
 - (15) giardiasis;
 - (16) gonorrhea;
 - (17) Haemophilus influenzae, invasive disease;
 - (18) hemolytic uremic syndrome, postdiarrheal;
 - (19) hepatitis B in pregnancy (report the pregnancy of each woman with hepatitis B);**

- (20) hepatitis, viral;
- (21) hantavirus pulmonary syndrome;
- (22) influenza, if the disease results in the death of any child under 18 years of age;
- (23) legionellosis;
- (24) leprosy or Hansen's disease;
- (25) listeriosis;
- (26) Lyme disease;
- (27) malaria;
- (28) measles or rubeola (report by telephone within four hours to the secretary);
- (29) meningitis, bacterial (indicate causative agent, if known, and report by telephone within four hours to the secretary);
- (30) meningococemia (report by telephone within four hours to the secretary);
- (31) mumps (report by telephone within four hours to the secretary);
- (32) pertussis or whooping cough (report by telephone within four hours to the secretary);
- (33) plague or Yersinia pestis (report by telephone within four hours to the secretary);
- (34) poliomyelitis (report by telephone within four hours to the secretary);
- (35) psittacosis;
- (36) rabies, animal and human (report by telephone within four hours to the secretary);
- (37) Rocky Mountain spotted fever;
- (38) rubella, including congenital rubella syndrome (report by telephone within four hours to the secretary);
- (39) salmonellosis, including typhoid fever;
- (40) severe acute respiratory syndrome (SARS) (report by telephone within four hours to the secretary);
- (41) shigellosis;
- (42) streptococcal invasive, drug-resistant disease from group A Streptococcus or Streptococcus pneumoniae;
- (43) syphilis, including congenital syphilis;
- (44) tetanus;
- (45) toxic-shock syndrome, streptococcal and staphylococcal;
- (46) any transmissible spongiform encephalopathy (TSE) or prion disease (indicate causative agent, if known);
- (47) trichinosis;
- (48) tuberculosis, active and latent (report active disease by telephone within four hours to the secretary);
- (49) tularemia;
- (50) varicella or chickenpox;
- (51) yellow fever; and
- (52) any exotic or newly recognized disease, and any disease unusual in incidence or behavior, known or suspected to be infectious or contagious and constituting a risk to the public health (report by telephone within four hours to the secretary).

(b) The occurrence of a single case of any unusual disease or manifestation of illness that the health care provider determines or suspects could be caused by or related to a bioterrorism act shall be reported within four hours by telephone to the secretary. The term "bioterrorism act," as used in this article, shall mean a dispersion of biological or chemical agents with the intention to harm. Each bioterrorism act shall be reported within four hours by telephone to the secretary. The following shall be considered ioterrorism agents when identified in the course of a possible bioterrorism act:

- (1) Anthrax;
- (2) plague;
- (3) smallpox;
- (4) tularemia;
- (5) botulism;
- (6) viral hemorrhagic fever;
- (7) Q fever or Coxiella burnetii;
- (8) brucellosis; and

(9) any other infectious or toxic agent that can be intentionally dispersed in the environment.

(Authorized by K.S.A. 65-101 and 65-128; implementing K.S.A. 65-118 and 65-128; effective May 1, 1982; amended May 1, 1986; amended Dec. 24, 1990; amended April 19, 1993; amended Jan. 12, 1996; amended Dec. 1, 1997; amended Feb. 18, 2000; amended, T-28-11-20-03, Nov. 20, 2003; amended March 5, 2004; amended April 28, 2006.)

HIPAA Regulation Section 164.512

Title 45 -- Public Welfare

Subtitle A -- Department of Health and Human Services

Subchapter C -- Administrative Data Standards and Related Requirements

Part 164 -- Security and Privacy

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: uses and disclosures for public health activities—*

(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include: (A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products; (C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or (D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation;

or (v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:

(1) To conduct an evaluation relating to medical surveillance of the workplace; or

(2) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(1) By giving a copy of the notice to the individual at the time the health care is provided; or

(2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

APPENDIX B
REPORTING FORMS



PRENATAL CARE PROVIDER REPORT FORM PERINATAL HEPATITIS B PREVENTION

Please complete the form with as much information as possible and FAX to the Perinatal Hepatitis B Prevention Program at **1-877-427-7318**.

PROVIDER'S NAME _____ PROVIDER'S PHONE NUMBER () _____

ADDRESS _____

TODAY'S DATE ____ / ____ / ____

MOTHER'S INFORMATION

Last Name:		First Name:	
Date of Birth: / /		HBsAg positive test date: / /	
Address:			
City:		Zip Code:	
Contact Phone #: ()		Alternative Phone #: ()	
Anticipated Delivery Hospital:			
Estimated Delivery Date: / /			
Anticipated Pediatrician Name:			
Anticipated Pediatrician Phone #: ()			
Insurance: <input type="checkbox"/> Medicaid <input type="checkbox"/> Private Insurance <input type="checkbox"/> Uninsured <input type="checkbox"/> Other (please specify) _____			
Race: (check all that apply)			Hispanic Ethnicity:
<input type="checkbox"/> African American or Black <input type="checkbox"/> Caucasian or White			<input type="checkbox"/> Yes
<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander			<input type="checkbox"/> No
<input type="checkbox"/> Asian <input type="checkbox"/> Race, not otherwise specified			

For questions or more information please call (785) 368-8208.



HOSPITAL REPORT FORM

PERINATAL HEPATITIS B PREVENTION

Follow-up of infants born to HBsAg positive mothers

Please complete the form with as much information as possible and FAX to the Perinatal Hepatitis B Prevention Program at **1-877-427-7318**.

<p>For Women Known to be HBsAg Positive:</p> <p><input type="checkbox"/> Administer hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of births to all infants.</p> <p>If the infant doesn't receive HBIG within 12 hours, it can be administered up to 7 days after birth.</p>	<p>For Women Whose HBsAg Status is Unknown:</p> <p><input type="checkbox"/> Perform a stat HBsAg screening test for all women admitted to delivery whose hepatitis B status is unknown.</p> <p><input type="checkbox"/> While test results pending, administer the hepatitis B vaccine to infant within 12 hours of birth. If the mother is discovered to be HBsAg positive then administer HBIG as soon as possible.</p>
---	--

HOSPITAL NAME _____ CITY _____

TODAY'S DATE ____ / ____ / ____

MOTHER'S INFORMATION

Last Name:	First Name:
Date of Birth: / /	HBsAg positive test date: / /
Address:	
City:	Zip Code:
Contact Phone #: ()	Alternative Phone #: ()
OB/GYN Name:	OB/GYN Phone #: ()
Insurance: <input type="checkbox"/> Medicaid <input type="checkbox"/> Private Insurance <input type="checkbox"/> Uninsured <input type="checkbox"/> Other (please specify) _____	
Race: (check all that apply)	
<input type="checkbox"/> African American or Black <input type="checkbox"/> Caucasian or White	Hispanic Ethnicity: <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander	
<input type="checkbox"/> Asian <input type="checkbox"/> Race, not otherwise specified	

INFANT'S INFORMATION

Last Name:	First Name:
Date of Birth: / /	Time of Birth:
Date of HBIG: / /	Time of HBIG:
Date of Hepatitis B1 vaccine: / /	Time of Hepatitis B1 vaccine:
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Insurance: <input type="checkbox"/> Medicaid <input type="checkbox"/> Private Insurance <input type="checkbox"/> Uninsured <input type="checkbox"/> Other (please specify) _____	
Pediatrician's Name	Pediatrician's Phone #: ()
IMPORTANT: Clinic where infant will receive Hepatitis B2 vaccine: _____	
Note: Hepatitis B2 vaccine is recommended at 1month of age.	

For questions or more information please call (785) 368-8208.



PEDIATRIC CARE REPORT FORM PERINATAL HEPATITIS B PREVENTION

PLEASE PLACE THIS REMINDER IN THE FRONT OF THE INFANT'S CHART

This newborn's mother is hepatitis B positive.

It is very important that **within the first 12 hours of birth**, this newborn receives one dose of **HBIG and the first dose of hepatitis B vaccine**. This infant will also need **two additional doses of hepatitis B vaccine to complete the series at approximately 1 month and 6 months of age**.

Following completion of the vaccination series, at age 9-18 months of age (generally the next well child visit), the child will need post vaccination serologic (PVS) testing: HBsAg and anti-HBs. This testing is done to confirm the child did not contract hepatitis B and that the child is protected from contracting hepatitis B in the future.

Note: An infant who does not receive the vaccine may become infected with hepatitis B virus and develop severe complications.

Please complete the form with as much information as possible and FAX with infant's lab results to the Perinatal Hepatitis B Prevention Program at **1-877-427-7318**.

PATIENT NAME: _____

DATE OF BIRTH: ___ / ___ / _____ Time: ___: ___ SEX: _____

RACE _____ ETHNICITY _____ PHONE: _____

ADDRESS: _____

INSURANCE (Please Circle): Private Medicaid Uninsured Other: _____

DELIVERY HOSPITAL: _____

HEPATITIS VACCINATION HISTORY (Please provide date given):

HBIG: Date: ___ / ___ / _____ Time: ___: ___

HEP B DOSE 1: Date: ___ / ___ / _____ Time: ___: ___

HEP B DOSE 2: ___ / ___ / _____ HEP B DOSE 3: ___ / ___ / _____

PVS Testing: Date ___ / ___ / _____ **HBsAg:** Positive Negative

Anti-HBs: Positive Negative

For questions or more information please call (785) 368-8208.

APPENDIX C KANSAS NOTIFIABLE DISEASE FORM

KANSAS NOTIFIABLE DISEASE FORM

Today's Date: ___ / ___ / ___

Patient's Name: _____ <div style="display: flex; justify-content: space-around; font-size: small;"> Last First Middle </div>		
Day Phone: _____		Evening Phone: _____
Residential Address: _____		
City: _____	Zip: _____	County: _____
Ethnicity:	<input type="checkbox"/> Hispanic or Latino	<input type="checkbox"/> Not Hispanic or Latino
Race: <i>(Circle all that apply)</i>		
<input type="checkbox"/> American Indian/Alaska Native	<input type="checkbox"/> Asian	<input type="checkbox"/> Black or African American
<input type="checkbox"/> Native Hawaiian or Other Pacific Islander	<input type="checkbox"/> White	<input type="checkbox"/> Unknown
Sex: M F	Date of Birth: ___ / ___ / ___	Age if DOB unknown: _____
Disease Name: _____		
Symptoms: Onset: ___ / ___ / ___ List the 3 most prominent symptoms:		
Symptom 1: _____ Symptom 2: _____ Symptom 3: _____		
Outbreak associated? Y N	Died? Y N	Hospitalized? Y N
Institutional Residence? None Nursing Home Correctional Residential Hospital Psych		
Physician Name: _____		Physician Phone: _____
Laboratory Information:		
Specimen Collection Date: ___ / ___ / ___		Date Reported To You: ___ / ___ / ___
Name of Test Performed: _____		Results of Test: _____
Name of Laboratory: _____		Laboratory Results Attached? Y N
Treatment Information:		
Date of Treatment: ___ / ___ / ___		Treatment Type and Dosage: _____
Treatment Status: Complete On-going Discontinued		

Name of person reporting: _____ **Phone:** _____

Comments: _____

Mail or fax reports to your local health department and/or to:
 KDHE Office of Surveillance and Epidemiology, 1000 SW Jackson, Suite 210, Topeka, KS 66612-1274
Fax: 877-427-7318 (toll-free) Epidemiology Hotline: 877-427-7317 (Revised 07/2008)

APPENDIX D
LETTERS FOR PROVIDERS

LETTER FOR PRENATAL CARE PROVIDERS

[Date]

[Dr. Name]

[Address]

[City, State, Zip]

Dear Dr. _____:

Your patient, [Patient Name, DOB] has tested positive for hepatitis B surface antigen (HBsAg).

It is extremely important that within the first 12 hours of birth, Ms. _____'s newborn receives one dose of hepatitis B immune globulin (HBIG) and the first dose of Hepatitis B vaccine. The infant will also need two additional doses of Hepatitis B vaccine to complete the series and testing to ensure the infant is protected from hepatitis B.

An infant exposed to hepatitis who does not receive the vaccine and HBIG may become infected with hepatitis B virus, which can result in severe complications including death. In Kansas, local public health departments work with parent(s) to ensure the infant completes three doses of the hepatitis B vaccine and is tested at 9-18 months of age to determine if the infant is protected.

We greatly appreciate your assistance in protecting this child. Please return this letter with the following information filled out. If you have any additional questions, please contact the health department.

Thank you,

[Disease Investigator]

TODAY'S DATE ____ / ____ / ____

MOTHER'S INFORMATION

Last Name:		First Name:	
Date of Birth: / /		HBsAg positive test date: / /	
Address:			
City:		Zip Code:	
Contact Phone #: ()		Alternative Phone #: ()	
Anticipated Delivery Hospital:			
Estimated Delivery Date: / /			
Anticipated Pediatrician Name:			
Anticipated Pediatrician Phone #: ()			
Insurance: <input type="checkbox"/> Medicaid <input type="checkbox"/> Private Insurance <input type="checkbox"/> Uninsured <input type="checkbox"/> Other (please specify) _____			
Race: (check all that apply) <input type="checkbox"/> African American or Black <input type="checkbox"/> Caucasian or White <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> Race, not otherwise specified			Hispanic Ethnicity: <input type="checkbox"/> Yes <input type="checkbox"/> No

LETTER FOR PEDIATRIC CARE PROVIDERS, PRE-DELIVERY

PLEASE PLACE THIS REMINDER IN THE FRONT OF THE BABY'S CHART

[Date]

Re: Expected newborn of [parent(s) names]

Dear Dr. []:

[Mother's name] is HBsAg positive with an expected delivery date of [EDD] at [delivery hospital].

It is very important that within the first 12 hours of birth, [Mother's name]'s newborn receives one dose of HBIG and the first dose of hepatitis B vaccine. This infant will also need two additional doses of hepatitis B vaccine to complete the series at approximately 1 month and 6 months of age.

Following completion of the vaccination series, at age 9-18 months of age (generally the next well child visit), the child will need post vaccination serologic (PVS) testing: HBsAg and anti-HBs. This testing is done to confirm the child did not contract hepatitis B and that the child is protected from contracting hepatitis B in the future.

Note: An infant who does not receive the vaccine may become infected with hepatitis B virus and develop severe complications.

Please call with questions or if you are aware of changes in the client's contact information. Please fax this page to (XXX)-XXX-XXXX following each immunization and post-vaccination serological testing.

Thank you for your assistance in protecting this child.

[Disease Investigator]
(XXX)-XXX-XXXX

PATIENT NAME: _____

DATE OF BIRTH: ___ / ___ / ___ Time: ___: ___ SEX: _____

RACE _____ ETHNICITY _____ PHONE: _____

ADDRESS: _____

INSURANCE (Please Circle): Private Medicaid Uninsured Other: _____

DELIVERY HOSPITAL: _____

HEPATITIS VACCINATION HISTORY (Please provide date given):

HBIG: Date: ___ / ___ / ___ Time: ___: ___

HEP B DOSE 1: Date: ___ / ___ / ___ Time: ___: ___

HEP B DOSE 2: ___ / ___ / ___ HEP B DOSE 3: ___ / ___ / ___

PVS Testing: Date ___ / ___ / ___ HBsAg: [] Positive [] Negative

Anti-HBs: [] Positive [] Negative

LETTER FOR PEDIATRIC CARE PROVIDERS, POST-DELIVERY

PLEASE PLACE THIS REMINDER IN THE FRONT OF THE BABY'S CHART

[Date]

Re: [Infant Name]

Dear Dr. []:

[Mother's name] is HBsAg positive and gave birth to [Infant Name] on [DOB] at [delivery hospital].

In addition to the first dose of hepatitis B and HBIG which were administered at the hospital, it is very important that this infant will receive **two additional doses of hepatitis B vaccine to complete the series at approximately 1 month and 6 months of age.**

Following completion of the vaccination series, at age 9-18 months of age (generally the next well child visit), the child will need post vaccination serologic (PVS) testing: HBsAg and anti-HBs. This testing is done to confirm the child did not contract hepatitis B and that the child is protected from contracting hepatitis B in the future.

Note: An infant who does not receive the vaccine may become infected with hepatitis B virus and develop severe complications.

Please call with questions or if you are aware of changes in the client's contact information. Please fax this page to (XXX)-XXX-XXXX following each immunization and post-vaccination serological testing.

Thank you for your assistance in protecting this child.

[Disease Investigator]

(XXX)-XXX-XXXX

PATIENT NAME: _____

DATE OF BIRTH: ___ / ___ / ___ Time: ___:___ SEX: _____

RACE _____ ETHNICITY _____ PHONE: _____

ADDRESS: _____

INSURANCE (Please Circle): Private Medicaid Uninsured Other: _____

DELIVERY HOSPITAL: _____

HEPATITIS VACCINATION HISTORY (Please provide date given):

HBIG: Date: ___ / ___ / ___ Time: ___:___

HEP B DOSE 1: Date: ___ / ___ / ___ Time: ___:___

HEP B DOSE 2: ___ / ___ / ___ HEP B DOSE 3: ___ / ___ / ___

PVS Testing: Date ___ / ___ / ___ **HBsAg:** Positive Negative

Anti-HBs: Positive Negative

LETTER FOR HOSPITALS

[Date]

[Infection Preventionist's Name]

[Hospital Name]

[Address]

[City, State Zip]

Dear [Hospital ICP]:

Following is information regarding an **HBsAg + PRENATAL** client who plans to deliver at your hospital.

Mother's name: _____ DOB: _____ EDD: _____

Father's name: _____

Physician's name: _____ Phone: _____

Pediatrician's name: _____ Phone: _____

This infant will need to be administered the hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth.

Please notify the **Health Department** of the client's delivery and fax the **Perinatal Hepatitis B Prevention Hospital Report Form** documenting **HBIG** and **hepatitis B** vaccination dates and times to the **Health Department** at **(xxx) xxx-xxxx**. Please call or email with questions.

Thank you for your assistance with this important program.

[Disease Investigator]

(xxx) xxx-xxxx.

APPENDIX E

ADDITIONAL RESOURCES

Kansas Department of Health and Environment

Home page: www.kdheks.gov

Infectious Disease Epidemiology and Response: <http://www.kdheks.gov/epi/index.html>

Viral Hepatitis Prevention/Perinatal Hepatitis B: <http://www.kdheks.gov/hiv/hepatitis.htm>

Immunization Program: <http://www.kdheks.gov/immunize/index.html>

Centers for Disease Control and Prevention

Home page: www.cdc.gov

National Immunization Program: www.cdc.gov/vaccines

Division of Viral Hepatitis: www.cdc.gov/hepatitis

Vaccine Information Statement (VIS): www.cdc.gov/vaccines/pubs/vis/default.htm

General Resources

Advisory Committee on Immunization Practices (ACIP): www.cdc.gov/vaccines/recs/acip/default.htm

American Academy of Pediatrics (AAP): www.aap.org

American College of Obstetrician and Gynecologist (ACOG): www.acog.org

American Liver Foundation: www.liverfoundation.org

Asian Liver Center at Stanford University: <http://liver.stanford.edu>

Hepatitis B Foundation: www.hepb.org

Hepatitis B Moms: www.hepbmoms.org

Hepatitis Foundation International: www.hepfi.org

Immunization Action Coalition: www.immunize.org

Pink Book-Epidemiology and Prevention of Vaccine-Preventable Diseases:

www.cdc.gov/vaccines/pubs/pinkbook/default.htm

Red Book-Report of the Committee on Infectious Diseases: www.aap.org/bookstorepubs.html